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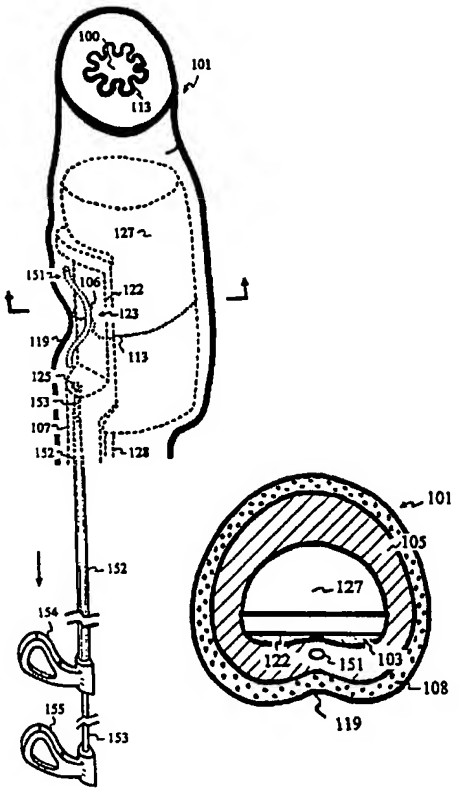
(54) Title: URETHRAL MUSCLE CONTROLLED MICRO-INVASIVE SPHINCTERIC CLOSURE DEVICE



(57) Abstract: A rod-like or tube-like sphincteric closure device (151) is micro-invasively implanted beneath the surface of the posterior mucosal wall (119) to elevate the mucosa (113) and close the lumen (100), by using a delivery device operated through the urethra (101). To initiate voiding, the muscle-rich anterior urethral wall contracts and widens the lumen beyond the closing or elevating range of the sphincteric closure device (151). For urethral obstruction, repelling magnets are micro-invasively implanted beneath the surface of mucosa with the delivery through the urethra, to widen the lumen with magnetic force.

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URETHRAL MUSCLE CONTROLLED MICRO-INVASIVE SPHINCTERIC CLOSURE DEVICE

FIELD OF THE INVENTION

This invention relates to rod-like or tube-like sphincteric closure devices implanted beneath the surface of the mucosa through the urethra with a micro-invasive delivery device. The sphincteric closure devices narrow or close the lumen opening to prevent urine leakage without interfering with the process of voluntary voiding.

BACKGROUND, TRADITIONAL TREATMENTS AND PRIOR INVENTIONS

Prevalence and Cost of Urinary Incontinence

Urinary incontinence is one of the most common urinary dysfunctions. The number of people living with urinary incontinence is far higher than estimated, even by most primary care physicians. A report published by the Agency for Health Care Policy and Research of the U.S. Public Health Service estimates that at least 10 million, more likely 20 million, adult Americans are affected by urinary incontinence. Many patients, especially women, do not mention their incontinence problems to their physicians. One of the reasons is that women are accustomed to using feminine hygiene products, some of which are designed for urine absorption. Among the elderly population, a 1975 report from the U.S. Department of Health showed that 55% of the surveyed patients living in long-term facilities had problems with urinary control. In 1980, a large European postal survey of 22,430 people from ages 5 to over 85 showed that up to 8.5% of surveyed individuals had two or more episodes of urinary incontinent occurrences in a month. The percentage of women within the age groups who suffer from occasional incontinence is much higher (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, pp.73-74).

Although urinary incontinence is not a life threatening disease, many incontinent patients suffer intense embarrassment, loss of self-esteem, feelings of helplessness, limitations on travel, depression, anxiety, avoidance of sexual relationships and withdrawal from social contacts (Urology Times, February 1996; Hu T-W., J. Am. Geriatr. Soc., 38:292, 1990).

Urinary incontinence is costly to patients and health care systems. Annual sales of adult disposable diapers reach half a billion dollars. The annual cost to the U.S. health care system for treating patients suffering from urinary incontinence exceeds $15 billion, according to a 1996 report "Urinary Incontinence in Adults Acute and Chronic Management", published by the Department of Health and Human Services. The indirect cost is likely to be much higher, in fact incalculable. The careers of the sufferers are often prematurely terminated or adversely affected by the offensive odor. The financial and social impact from urinary incontinence are very real, significant and rapidly growing as our population ages.

Mechanism of Urethral Sphincter

The two major urinary closures in our bodies are the urethral sphincter and the bladder neck. The urethral sphincter is often perceived as a mechanical valve, which stops the flow of urine from the bladder. However, unlike the valves of a heart, the urethral sphincter cannot be identified with the naked eye or even under a microscope. The interior layer of the urethra is an integrated interaction between smooth and striated muscle with collagen and elastin forming spongy and supple mucosal folds, which actuate the closure of the urethral lumen. The exterior or outer layer of the urethra provides structural and ligamental support. The external striated layer of the urethral sphincter consists of bundles of circularly arranged fibers with maximal density at the mid-urethral level anteriorly, thinning laterally and becoming almost totally deficient posteriorly (Gosling J. A., et al., J. Anat. 129:216, 1979; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, pp. 4-5). Slow-twitch muscle fibers primarily provide involuntary urinary sphincteric control; fast-twitch fibers are responsible for voluntary sphincteric activity. Therefore, the sphincter is under partial voluntary control. (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, pp. 58-59).

The female urethra is between 30 and 50 mm in total length, including the sphincteric length of about 28 mm, with the lumen diameter being about 5.3 mm. The sponge-like folding and suppleness of the resilient mucosa are promoted and maintained by sex hormone. With age and the declining level of sex hormone, the mucosa of the middle and proximal portions of the urethra thins out (Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 5).

During stress from suddenly increasing abdominal pressure, such as coughing or sneezing, the tensile forces of the urethropelvic ligaments pull on the urethra laterally and collapse the

opening of the lumen, as indicated in Figure 2. The spongy mucosa in the lumen forms a coaptive seal to prevent urine leakage (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p. 66).

On the other hand, voiding is accomplished by the relaxation of pelvic floor muscles, contraction of detrusor muscles from the abdomen and increased tension of urethral muscles to shorten and widen the urethra (Lapides J., J. Urol. 80:341-353, 1958; Bradley W. E., et al., Urol. Clin. North. Am., 1: 3-27, 1974; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 11).

Urinary control is a complex mechanism that involves the bladder neck, proximal urethral smooth muscle and anatomic support of both the bladder base and urethra. Circular fibers of smooth muscle are found in the bladder neck. It seems that passive elastic tension is the most important factor leading to closure of the bladder neck and proximal urethra.

The bladder neck and the proximal urethra retain sphincteric function unless they are damaged by disease, surgery, pregnancy or by the constant pull of gravity on the muscular and ligamental supports (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1007).

Factors Leading to Urinary Incontinence

The following elements are essential for apposition and coaptation of the mucosa: urethral wall tension, external compression, urethral support, adjustment during increased abdominal pressure and suppleness of the mucosa (Zinner N. R., et al., Urology, 1980, 16:115; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1017).

It is widely believed that a leading cause of urinary incontinence is the loss of structural support for the urethra, especially behind the posterior urethral wall, which is indicated by hypermobility of the urethra. Gravity and/or pregnancy may adversely affect the structural support. As a result, descent of the bladder neck and urethra in varying degrees lead to varying types of stress incontinence (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1018; Walters M. D., J. Repro. Med. 1990, 35(8): 777-784).

The structural (anatomic) support of the muscle-poor posterior urethral wall serves as a backboard against which the urethra is compressed during increased abdominal pressure. Research studies using magnetic resonance imaging substantiate the importance of posterior support of the urethra. During stress in the incontinent patient, there is an unequal movement of the anterior and posterior walls of the vesical (bladder) neck and urethra proximal to the bladder. The urethral lumen is actually pulled open as the posterior wall moves away from the anterior wall; then leakage

occurs (Mostwin J. L. et al., Urol. Clin. North. Am. 1995, 22(3): 539-549; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018).

In men, sphincteric abnormalities are most commonly caused by anatomic disruption after prostate surgery, trauma or neurologic abnormalities. After radical prostatectomy, five to ten percent of the patients suffer from permanent urinary incontinence. In women, sphincteric abnormalities may be classified in two ways: (1) urethral hypermobility, and (2) intrinsic sphincter deficiency. Urethral hypermobility is often caused by a weakness of pelvic floor support. During an increase in abdominal pressure, vesical neck and proximal urethra rotationally descend and slip away from the posterior support. (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1011-1012).

Incontinence that occurs during stress is not always caused by the lack of anatomic support or sphincteric abnormalities. In some patients, stress initiates an abdominal detrusor contraction. This condition has been called stress hyper-reflexia. Stress incontinence and hyper-reflexia are easily differentiated. If the leakage stops as soon as the stress is over, it is stress incontinence. If voiding uncontrollably follows the stress, it is hyper-reflexia or detrusor hyperactivity, a common condition especially among the elderly (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1023; Raz p. 231).

In one study of incontinent women, 38% had mixed hyper-reflexia and stress incontinence, and 16.5% had hyper-reflexia alone as the cause of the incontinence (Sand P. K., Obstet. Gynec., 70:57, 1987). Although genuine stress incontinence is probably the most common cause of urinary incontinence in women, the incidence and prevalence of detrusor hyperactivity increases with age (Bates C. P., Clin. Obstet. Gynecol., 5:109, 1978).

Diagnosis of Urinary Incontinence

Physical examination, urodynamics (study of urine propulsion and flow) and cystoscopy (endoscopy for the urinary tract) are commonly used to determine the true nature of the patient's stress incontinence and to guide in the choice of treatment.

To determine urethral hypermobility, a cotton-swab test is used in physical examination. A well-lubricated and sterile cotton-swab is inserted into the urethra. During coughing, an unstable urethra sways and is evident by the outer portion of the cotton swab. If the sway is greater than 15 degrees, the patient has urethral hypermobility.

Cystometry is a urodynamic method used to measure intravesical bladder pressure during the course of bladder filling. The filling medium may be carbon dioxide or a liquid, such as water,

saline or radiographic contrast material. Pressure is measured during and after filling (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.934). With about 200 ml filling medium in the bladder and about 55-cm water pressure, stress is initiated. If voiding stops at the end of the stress, the patient has stress incontinence, which indicates intrinsic sphincter deficiencies (ISD). If voiding continues after the stress ceases, it is likely detrusor hyperactivity, or hyper-reflexia. To determine the degree of incontinence, the fill volume and pressure is increased to the point where involuntary voiding occurs; this is defined as the leak-point pressure in urodynamics.

Classification of Stress Incontinence

To evaluate the degree of bladder/urethral support and sphincter competence, stress incontinence is divided into the following five classifications. Type 0: Patient complains of stress urinary incontinence. Videourodynamic testing reveals that both the vesical neck and proximal urethra are closed at rest and situated at or above the lower end of the pubis symphysis. During stress, the vesical neck and proximal urethra descend and open, assuming an anatomic configuration similar to that seen in types I and II stress urinary incontinence, but with no urine leakage. Type I: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra open and descend less than 2 cm. Urinary incontinence is apparent with increased abdominal pressure. Type IIA: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra are also open, but with a rotational descent characteristic of a cystourethrocele (prolapse of bladder and urethra) which accompanies urine leakage. Type IIB: The vesical neck is closed at rest but situated at or below the inferior margin of the pubis symphysis. During stress, there may or may not be further descent, but the proximal urethra opens and incontinence ensues. Type III: The bladder neck and urethra are open at rest indicating intrinsic sphincter dysfunction with or without hypermobility. Obvious urinary leakage is associated with minimal abdominal pressure (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1013-1016; Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p.345).

Non-Surgical Treatments

Non-surgical treatments include (1) pelvic floor exercise to strengthen pelvic muscles, (2) estrogen to thicken mucosa, (3) biofeedback and/or electrical stimulation to stimulate certain sets of urethral muscles, (4) alpha-sympathomimetic drugs for intrinsic sphincter deficiency, and (5) mechanical devices to clamp the urethra.

Pelvic floor exercise and estrogen may have value as preventive measures. Biofeedback and electrical stimulation have been reported to cause improvement in 30% to 75% of patients; but only about 10% of patients experience a "cure" with little long-term data confirming the claims. Drug therapy has very limited success and significant side effects.

Urethral removable plugs (US patent 5,562,599 to Beyschlag, US patent 4,457,299 to Cornwell, US patent 5,131,906 to Chen, US patent 5,906,575 to Conway et al., US patent 5,885,204 to Vergano) are uncomfortable and troublesome to use, and their use increases the possibility of urinary tract infections. Penile clamping devices (US patent 4,942,886 to Timmons) are also highly uncomfortable and unnatural and may even cut off blood supply. For females, pessary devices (US patent 5,007,894 to Enhorning, US patent 5,386,836 to Biswas, US patent 5,785,640 to Kresch et al.) are designed to be worn in the vagina to compress and stop the leakage of urine. To be effective, the compression has to be strong and uncomfortable. Similar to the urethral plugs, pessary devices increase the possibility of infections and are troublesome to use, messy during menstrual periods.

Surgical Treatment

In general, surgical treatments for urinary incontinence are far more successful than existing non-surgical treatments and are the only reasonable long-term solution thus far. The primary goals of the surgical approaches for sphincteric incontinence are (1) to correct urethral hypermobility and the excessive anatomic descent of the bladder neck/urethra, and (2) to increase urethral resistance by improving urethral coaptation and compression for treating intrinsic sphincteric dysfunction (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018, p.1066). Surgical procedures designed to meet these two simple goals differ in their suture material, placement, depth, distance from urethra and location of abdominal anchoring sites.

For anatomic corrections, sutures are used to pull and lift the vaginal wall forward and upward along with the urethra and bladder neck. In essence, the vaginal tissue serves as the supporting backboard for the urethra. Sutures are then fastened onto abdominal tissue or the pubis symphysis. The major differences between surgical procedures of this type are the location of incisions, vaginal suspension, transvaginal suspension, and requirement of tissue dissection.

Burch and Marshal-Marchetti-Krantz procedures use the vaginal-abdominal approach requiring abdominal incisions; while Raz suspensions, Stamey needle and Gittes needle are the transvaginal suspension procedures. Some surgeons prefer opening both abdominal and vaginal cavities.

Several less invasive needles and devices (US patent 5,860,425, US patent 5,836,314 to Benderev et al., US patent 5,816,258 to Jervis, US patent 5,697,931 to Thompson, US patent 5,647,836 to Blake and US patent 5,549,617 to Green et al.) are designed to pull the urethra forward by pulling the vaginal anterior wall forward. Without a direct view of the surgical site, one of the major potential problems with the devices is the uncertainty of suture tension, let alone obtaining the optimal suture tension. If the suture is too tight, the urethra is too restricted, and urinary obstruction occurs. Removing existing sutures with surrounding fibrotic tissue formation is an invasive surgery. If the tension is too loose, incontinence continues.

Common anatomic surgical complications include recurrent or persistent urinary incontinence, irritation, urinary retention, obstruction and/or persistent postoperative pain, which may be caused by urethral kinking, improper suture placement or improper tension. Other complications, such as wound infection, abscess formation, genitofemoral nerve entrapment, bladder leakage or urethral damages, are common occurrences as well (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1100). The overall complication rate ranges from 3% to 32% (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101). Furthermore, due to depth and axis alteration, numerous vaginal posterior prolapses have been reported following anatomic correction (Langer R. et al., Obstet. Gynecol. 1988, 72:866-869; Wiskind A. K., et al., Am. J. Obstet. Gynecol., 1992: 167:399-405; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101).

For intrinsic sphincter dysfunction, merely anatomic correction supported by a wall of soft vaginal tissue is inadequate. Therefore, sling procedures have been designed to loop behind the urethra and fasten onto the abdominal tissue. The loop forms a relatively firm backboard, which compresses and restricts the urethral sphincter. Slings are also effective in treating neurogenic intrinsic sphincter deficiency, such as myelodysplasia, a defective development of the lower segment of the spinal cord, (Gormley E. A., J. Urol. 1994, 152:822; McGuire E. J., J. Urol., 1987, 138:525-526; McGuire E. J., J. Urol., 1986, 135:94). A less invasive sling needle (US patent 5,899,909 to Claren et al.) has been invented to treat female sphincteric deficiency. Another invention (US patent 5,934,283 to Willem et al.) utilizes various materials, including autologous, heterologous or artificial material to construct a sling.

Common complications of the slings include sensations of inguinal pulling, potential erosion of the urethra, urinary retention, urethral obstruction and enterocele (posterior vaginal hernia). Most of these complications are once again due to improper tension of the suture or sling. If the

sling is too tight, the urethra is obstructed; if it is too loose, incontinence continues. Unfortunately, no standard parameters exist to identify the appropriate sling tension. Thus, it remains more an art than a science, with a limited margin of error.

In many failed sling procedures in the past, sutures attaching the urethra to the abdominal ligaments were too close to the urethra. Due to the close proximity of the suture and the pliable nature of the urethra, the tension of the suture created kinks in the urethra, resulting in urinary obstruction. Furthermore, the rubbing of the abdominally anchored suture onto the urethra is presumably the cause of fibrotic tissue formation around the urethra and sometimes urethral erosion to the point of severance.

Two other techniques, injectable materials and artificial sphincters, are often used to treat intrinsic sphincter deficiency. Injectable or bulking agents, such as collagen, polytetrafluoroethylene (PTFE), autologous fat and silicone, are injected into the wall of the bladder neck or urethral mucosa to decrease the size of the lumen opening and provide a more manageable or controllable sphincter. However, multiple injections are usually necessary for achieving noticeable improvement, especially in males. Furthermore, all these bulking agents migrate or metabolize away, some in less than a few months. Collagen begins degradation in twelve weeks. PTFE migrates and granuloma forms (Malizia A. A. Jr., et al., JAMA 1984, 251:3277-3281). Silicone polymers migrate and deposit in the lungs, kidneys, brain and lymph nodes.

Usually when all else fails in treating intrinsic sphincter deficiency, an artificial sphincter is implanted beneath the bladder neck around the urethra to mechanically pinch or restrict the opening of the lumen. Numerous artificial sphincters (US patent 5,893,826 to Salama, US patent 5,704,893 to Timm, US patent 5,562,598 to Whalen et al., US patent 5,097,848 to Schwarz, US patent 4,994,020 to Polyak, US patent 4,705,518 to Baker et al., US patent 4,632,114 to Todd et al. and US patent 4,552,128 to Haber) have been designed to restrict the urethra mechanically.

Implantation of an artificial sphincter is invasive surgery. Typically, an inflatable cuff is inserted around the bulbous urethra in the male or the bladder neck in the female. The tubing, liquid reservoir and pumps are implanted in the abdomen. Hospital post-surgical care lasts around three days.

Post-surgical complications include hematoma, cuff erosion, tissue atrophy, early infection from surgical contamination, late infection from urinary tract origin and mechanical malfunction, such as tube kinking or leaks (Carson C. C., Urol. Clin. North. Am., 1989, 16:139-147). Tissue

atrophy, a natural result of cuff compression over time, is often followed by cuff erosion with symptoms of pain, swelling, infection and/or bloody discharge. Confirmation of erosion mandates cuff removal (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1131-1132).

To maximize the longevity of the artificial sphincter, multiple life-long restrictions, which includes deactivation of the sphincter as often as possible and avoidance of bicycle riding, horseback riding and prolonged sitting are imposed. Furthermore, during pregnancies, the sphincter needs to be deactivated during the last trimester, and delivery by cesarean section is strongly recommended (Barrett D. M., et al., Urol. Clin. North. Am., 1989, 16:119-132; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1111 and p.1130-1131).

Urethral Obstruction

One of the most common urinary dysfunctions among middle aged and elderly men is urethral obstruction; and the most common cause of the obstruction is lumen narrowing of the supple urethra by an enlarged prostate, a condition called benign prostatic hyperplasia (BPH). Two classes of drugs are available to ease the urethral blockage. Alpha-blockers, such as phenoxybenzamine, prazosin, terazosin and doxazosin, are used to relax smooth muscles such as the one around the prostate, thus minimizing the restriction around the urethra. However, alpha-blockers have the side effect of hypotension, characterized by dizziness. Within the androgen suppression class of drugs, Finasteride is the only one with clinically acceptable tolerance. Androgen suppression causes a reduction in prostate volume, hence reducing the obstruction around the urethra. The primary side effects of androgen suppression are impotence and decreased ejaculatory volume.

Urethral stents, the only non-invasive device, are used to open the restricted urethra within the benign prostatic hyperplasia. However, given time, epithelial tissues grow into the lumen of the stents, requiring traumatic surgical removal. Several minimally invasive treatments, including high intensity ultrasound, laser, hyperthermia, thermotherapy, electro-vaporization, radio-frequency ablation and balloon dilation, have been invented for BPH. However, surgical transurethral resection of the prostate has been and still is the gold standard in terms of improving flow rate and decreasing postvoid residual urine.

SUMMARY OF INVENTIONS

A rod-like and a tube-like sphincteric closure devices are implanted beneath the surface of the urethral mucosa with a delivery device using micro-invasive methods to elevate the mucosa and

close the lumen of the urethra, without interfering with the voluntary muscular contraction for voiding. To urinate, the muscle-rich anterior urethral wall stiffens and widens to enlarge the lumen beyond the range of elevation from the sphincteric closure devices.

One of the sphincteric closure devices is made with two attracting magnets sandwiching the lumen to assist with lumen closure. By reversing the polarity of one of the magnetic devices, the magnetic devices repel each other from beneath the mucosa to open the lumen and push against urethral obstruction, such as that found in benign prostatic hyperplasia.

Arch Closure Device

An arch is made with elastic or shape memory material capable of being resiliently straightened in a needle equipped with a plunger for delivery. To assure that the curvature of the arch is bent toward the proper direction during delivery, the arch and the passage of the needle can be made non-round or elliptical to prevent arch rotation within the needle.

The arch, needle and plunger assemblies are parts of a delivery device with a balloon behind an indented pocket or recessed region. After insertion of the device into the urethra, the balloon is inflated from behind the indented recess, pushing and embedding the recess into the mucosal tissue. The indented recess holds or shelters a portion of mucosa and other soft urethral tissue from being flattened by the compression. The needle and the arch are then advanced through a hole in the proximal recessed wall to longitudinally penetrate beneath the surface of the loosely packed mucosa within the recessed pocket. To deploy the resiliently straightened arch, the needle is withdrawn while the plunger is held stationary behind the arch. As a result, the arch resumes the pre-disposed curvature toward the lumen, beneath the surface of the mucosa. After the balloon is deflated, the delivery device is withdrawn. The curvature or bend of the arch protrudes from within the urethral wall, elevating or lifting the mucosa to narrow or close the lumen, preventing or minimizing urine leakage. For voiding, the urethral muscles stiffen the urethra and significantly widen the lumen beyond the closing range of the arch. As a result, urine passes.

Arch Tube Closure Device

An arch tube is also made with elastic or shape memory material capable of being resiliently straightened by a rigid trocar passing through its passage for delivery. To ensure the curvature of the arch tube is bending toward the proper direction during delivery, the trocar and the passage of the arch tube can also be made non-round or elliptical to prevent rotation of the arch tube around the trocar.

The trocar and the arch tube are loaded as parts of a delivery device, similar to the one previously mentioned, equipped with a balloon behind an indented pocket or recessed region. The balloon is used to compress or position the recess into the soft urethral tissue, holding and sheltering the mucosa from flattening. The trocar is then advanced from a hole in the recess wall, penetrating beneath the loosely packed urethral tissue in the recess. The resiliently straightened arch tube is slid into position over the deployed trocar, both beneath the surface of the mucosa. While holding the arch tube stationary, the trocar is withdrawn, allowing the arch tube to resume the pre-disposed curvature toward the lumen beneath the mucosa. After the balloon is deflated, the delivery device is withdrawn. Similar to the arch, the arch tube also curves or bends toward the lumen, lifting the mucosa upward to coapt, narrow or close the lumen of the urethra, thus preventing or minimizing urine leakage.

Swellable Closure Device

A tube-like or rod-like swellable device is implanted beneath the surface of the mucosa with the delivery device. After hydration within the urethral tissue, the swollen device increases greatly in size, pressing against the surrounding tissue, especially into the vacant lumen space. As a result, the lumen is significantly narrowed or closed by the swollen device.

Inflatable Closure Device

Similar to the swellable device, an inflatable closure device is implanted beneath the surface of the mucosa with the delivery device. After the device is inflated by air, gas or liquid, it expands and pushes upon the surrounding tissue, particularly toward the direction of the vacant lumen space, to narrow or close the lumen.

Magnetic Closure Device

Two magnets with attractive polarities are implanted with the delivery device beneath the mucosa, one on each side of the urethra, sandwiching and compressing the lumen to improve closure and minimize urine leakage. Due to the relatively small urethral diameter, the magnetic forces created by the implanted magnets are strong and can be effectively assisting lumen closure.

Retrieval of Sphincteric Closure Device

For some adverse events, retrieval of the sphincteric closure device may be necessary. For ease of retrieval, a suture can be attached to the proximal end of the device. By pulling on the suture, the closure device can slip out from the soft urethral tissue, without invasive surgery. The biodegradable suture will be eliminated by cutting, urine excretion and/or biodegradation, while the sphincteric closure device remains in place.

Urinary Obstruction

Most of the urinary obstruction in men is caused by the enlargement of the prostate encroaching and pinching both the urethra and lumen opening. By reversing the polarities of the magnets, instead of attraction for lumen closure, the magnets repel each other, pushing the urethral wall outward to open the lumen, restoring urine flow.

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Posterior side of the arch	157
Lateral side of the arch	158
Panel-restricting tube	159
Receiving trough	160

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 indicates a normal, well-supported bladder **111** in dashed lines and a descended bladder **111** with a widened bladder neck **112** in solid lines.

Figure 2 shows a failed lumen **100** closure and hypermobility under stress with the urethropelvic ligament **102** pulling the lateral walls **131** of the poorly supported urethra **101**.

Figure 3 indicates a mid-longitudinal view of Figure 2 and urine **117** leakage during stress with urethropelvic ligaments pulling perpendicularly above and below the plane of the page.

Figure 4 shows a traditional surgical procedure for the treatment of urinary incontinence, using sutures **21** to pull the vagina **114** forward, supporting or gently compressing the urethral posterior wall.

Figure 5 depicts a section of the surgically corrected urethra **101** with sutures **21** pulling the vaginal **114** tissue to support and gently compress the urethral posterior wall **119**.

Figure 6 indicates the lumen **100** closure of the surgically corrected urethra **101** under stress, with urethropelvic ligaments **102** pulling the lateral walls **131** of the supported urethra **101**.

Figure 7 shows another surgical approach to narrowing the enlarged opening of the bladder neck **112** by looping a padded **145** suture **21** sling around the neck **112**.

Figure 8 depicts the injection of bulking agent **140** within the wall of the urethra **101** and bladder neck **121** to narrow the lumen **100**, monitored by an endoscope **138**.

Figure 9 indicates an arch **151** composed of legs **148** and an elastic or shape memory curvature **106**, with length L, height of curvature, H, and diameter, D.

Figure 10 shows the resiliently straightened arch **151** in a needle **152** with a plunger **153**.

Figure 11 depicts the deployment of the arch **151** by withdrawing the needle **152** while holding the plunger **153** stationary behind the arch **151**. The arch **151** resumes the pre-disposed curvature **106**.

Figure 12 indicates a delivery device **107** equipped with an arch **151** and a plunger **153** in a needle **152** adjacent to a tubing **128** for inflating and deflating a balloon **127**.

Figure 13 shows the inflated balloon **127** behind an indented recess **123** of the delivery device **107**.

Figure 14 depicts the advancement of the needle **152** with the arch **151** through the recess **123**, by pushing a needle advancer **154**.

Figure 15 indicates the deployment of the arch **151** by withdrawing the needle **152** while the plunger **153** is held stationary behind the arch **151**. The arch **151** then resumes the pre-disposed curvature **106**.

Figure 16 shows the deflation of the balloon **127**.

Figure 17 depicts a cross-section of a urethra **101** with multiple layers of tissue.

Figure 18A shows the insertion of the delivery device **107** into a urethra **101** before inflating the balloon **127**. A cross-section is marked 18B, as shown in Figure 18B.

Figure 18B depicts the cross section of a urethra **101** showing the mid-cross-section of the indented panel **122** and the balloon **127**, as marked in Figure 18A.

Figure 19A indicates the inflated balloon **127** compressing the ends of the indented recess **123** into the urethral wall. Within the recess **123**, the mucosa **113** is sheltered from compression, shown as a plane of mucosa **113** in a rippled dotted line around the recess **123**.

Figure 19B shows a cross section of Figure 19A with the inflated balloon **127** pushing the recess into submucosa **103** to store and loosely pack the soft urethral **101** tissue on the indented panel **122**.

Figure 20A indicates the penetration of the needle **152** with the arch **151** beneath the surface of loosely packed mucosa **113** in the recess **123**.

Figure 20B depicts the cross section of Figure 20A with the arch **151** inside the needle **152** advanced into the smooth muscle **105** within the recessed region.

Figure 21A shows the withdrawal of the needle **152** by retracting the needle advancer **154** while the plunger **153** is held stationary, allowing the curvature **106** to elevate the mucosa **113** toward the panel **122**.

Figure 21B indicates a cross section of Figure 21A with the arch **151** lifting the submucosa **103** and smooth muscle **105** toward the panel **122** of the recessed region.

Figure 22A indicates a deflated balloon **127** and the deployed arch **151** implanted beneath the surface of mucosa **113**, detached from the delivery device **107**.

Figure 22B shows a cross section of Figure 22A, indicating the lifting of the smooth muscle **105** and submucosa **103** by the arch **151** toward the center of the urethra **101**.

Figure 23A depicts the arch **151** implanted beneath the surface of mucosa **113** bending to close the lumen **100** after withdrawal of the delivery device.

Figure 23B indicates a cross section of Figure 23A showing lumen **100** closure by the lifting of the arch **151** upon the mucosa **113**, submucosa **103** and smooth muscle **105**.

Figure 24 depicts the activation of detrusor contraction **147** and urethral **101** muscles to widen the lumen **100** beyond the elevated range of the arch **151** to void.

Figure 25 shows a delivery device **107** with orientation line **130** and penetration markers **129**.

Figure 26 depicts a delivery device **107** with two deployment openings **125** for passage of two needles **152** housing arches **151** within them.

Figure 27 indicates a cross section of a closed lumen **100** with a large portion of urethral **101** tissue
lifted by two arches **151** to ensure lumen **100** closure.

Figure 28 depicts an arch **151** with a suture **21** attached.

Figure 29 shows anchoring devices **149** on an arch **151** for maintaining position and preventing migration.

Figure 30A indicates an arch **151** designed with lateral edges **158** for tissue anchoring to resist rotation of the curvature **106** away from the lumen. A cross section is shown in Figure 30B.

Figure 30B depicts a cross section of Figure 30A with lateral edges **158** for tissue anchoring and a mucosal lifting anterior **156** side.

Figure 31 shows a cross section of a curvature of another arch **151** with a tissue-trapping anterior **156** valley to prevent shifting of the curvature from facing the lumen to rotating to the side.

Figure 32 indicates an arch **151** with tissue ingrowth openings **150** to resist curvature **106** shifting or arch **151** migration with time.

Figure 33 depicts an arch **151** with a narrow curvature **106** and wide legs **148** to further stabilize the implant.

Figure 34A shows a resiliently straightened or flattened curvature **106** within the body of an arch **151**.

Figure 34B indicates a deployed curvature **106** protruding from the body of the arch **151**.

Figure 35 indicates an arch tube **104** with legs **148**, an elastic or shape memory curvature **106** and a central passage **144**. The dimensions are length, L, height of curvature, H, and diameter, D.

Figure 36 shows the resilient arch tube **104** straightened by the insertion of a rigid trocar **109**.

Figure 37 depicts a delivery device **107** equipped with the arch tube **104**, trocar **109** and tubing **128** for inflating and deflating a balloon **127**.

Figure 38 indicates the inflated balloon **127** behind an indented recess **123** of the delivery device **107**.

Figure 39 shows the deployment of the trocar **109** through the indented recess **123** by pushing in the trocar advancer **110**.

Figure 40 depicts the advancement of the resiliently straightened arch tube **104**, pushed by a device advancer **120**, sliding over the trocar **109** into the recess **123**.

Figure 41 shows the withdrawal of the trocar **109** while holding the device advancer **120** stationary to release the arch tube **104**, allowing the arch tube **104** to resume the pre-disposed curvature.

Figure 42 indicates a suture **21** attached to an arch tube **104**.

Figure 43 shows an elliptical arch tube **104** used to elevate mucosa to close the lumen.

Figure 44 indicates an arch tube **104** with a lengthened elastic curvature **106** to increase the length of sphincteric closure action.

Figure 45 depicts double elastic curvatures **106** to double the sphincteric closure action.

Figure 46 shows triple closure action from both legs **148** and the curvature **106**.

Figure 47 indicates an elastically curved **106** strip for elevating mucosal tissue to close the lumen.

Figure 48 shows a modular arch tube **104** to accommodate length-wise movement of the urethra.

Figure 49 depicts a urethral support **146** to strengthen the urethral wall.

Figure 50 shows a swellable closure device **134** around a trocar **109**.

Figure 51 indicates a cross section of a urethra **101** implanted with a swellable closure device **134** beneath the mucosal **113** surface.

Figure 52 depicts the enlargement of the swollen closure device **134** after absorption of water or blood serum.

Figure 53 shows a cross section of lumen **100** closure from compression by the enlargement of the swollen closure device **134**.

Figure 54 indicates an inflatable implant **135** around the trocar **109**.

Figure 55 depicts the inflated implant **135** with a one-way valve **141** within a stem **136** connected to a detachable tube **137**.

Figure 56 indicates a mid-longitudinal view of a recess positioner **142** above the delivery device **107**, positioned for urethral insertion.

Figure 57 shows the position of the recess positioner **142** for pushing the recess **123** of the delivery device **107** into the mucosal tissue.

Figure 58 shows a resilient panel **122** outside a panel-restricting tube **159**.

Figure 59 indicates the resiliently straightened panel **122**, shown in Figure 58, within the panel-restricting tube **159**.

Figure 60 depicts the delivery of the resiliently straightened panel **122** in the panel-restricting tube **159** into the urethra **101**.

Figure 61 shows the deployment of the resilient panel **122** with distal and proximal ends of the recess **123** embedded beneath the surface of mucosal **113** tissue by the withdrawal of the panel-restricting tube **159** within the urethra **101**.

Figure 62 indicates the advancement of the arch **151** in the needle **152** into the recess **123** under the surface of the mucosa **113**.

Figure 63 depicts the deployment of the arch **151** beneath the surface of the mucosa **113** by withdrawing the needle **152** while holding the plunger **153** behind the arch **151** stationary.

Figure 64 shows the retrieval of the resilient panel **122** by withdrawing the delivery device **107** into the panel-restricting tube **159**, while the arch remains and elevates the mucosal **113** tissue.

Figure 65 indicates a delivery device **107** with a built-in recess **123** and a receiving trough **160** open from the recess **123** to the distal end of the delivery device **107**.

Figure 66 shows a magnet **132** to be delivered into the urethral wall by the trocar **109** and delivery device.

Figure 67 depicts a pair of magnets **132** attracting each other.

Figure 68 shows a cross section of magnetic lumen **100** closure constricted by two attracting magnets **132** within anterior **118** and posterior **119** urethral walls.

Figure 69 depicts the mid-longitudinal view of two magnets **132** and delivery devices **107**, one above the other, facing opposite directions during urethral **101** insertion.

Figure 70 indicates mutual packing of mucosa **113** into both recesses **123** of the delivery devices **107** as they align with each other. Both trocars **109** are in position to be inserted beneath mucosal **113** surfaces within the recesses **123**.

Figure 71 shows a swellable closure device **134** and a magnet closure device **132** with sutures **21** attached for ease of retrieval.

Figure 72 depicts a swellable **134** and a magnetic **132** closure device with biodegradable coatings for direct penetration into the urethral wall.

Figure 73 indicates a compressed urethra **101** and a restricted lumen **100** encroached upon by the enlarged prostate **124**.

Figure 74 shows four magnets **132** arranged in repelling polarities beneath the mucosa **113** to open or enlarge the lumen **100**.

Figure 75 depicts anchoring devices **149** and tissue ingrowth openings **150** on the magnet **132** to minimize device migration.

DETAILED DESCRIPTION OF THE EMBODIMENTS

It is widely believed that most of the urinary incontinence in women is related to the descended position of the bladder **111**, the funneling of the bladder neck **112** and/or diminishing posterior **119** urethral support. The dashed line of Figure 1 indicates the normal position and the solid line depicts the descended position of the bladder **111** with its funnel-shaped bladder neck **112**. Figure 2 shows a failed lumen **100** closure and hypermobility under stress with the urethropelvic ligament **102** pulling the lateral walls **131** of the poorly supported urethra **101**. The mid-longitudinal view of Figure 2 during stress is shown in Figure 3, with urethropelvic ligaments pulling perpendicularly above and below the plane of the page. A section of poorly-supported posterior wall **119** withdraws from mucosal **113** coaptation, leading to urine **117** leakage.

Numerous prior art surgical procedures are designed to treat urinary incontinence. The traditional surgical treatment for urinary incontinence is to add backboard support to the urethral

posterior wall **119**, usually by repositioning the vagina **114** with sutures **21**. Figure 4 indicates the pre-surgical position of the vagina **114** with a dotted line, and that of the urethra **101** and bladder with dashed lines. The post-surgical positions of the vagina **114** and vaginal backboard-supported urethra **101** are depicted with solid lines. Figure 5 indicates a section of the vaginal backboard-supported posterior wall **119**. This significantly invasive procedure provides the backboard support needed for urethral sphincteric closure during stress with concurrent pulling of the urethropelvic ligament **102**, as shown in Figure 6. The sling procedure is designed to loop a suture **21**, tissue or other material behind the bladder neck **112** or urethra **101** to gently compress and restrict the lumen. Figure 7 illustrates the sling correction from a pre-surgical position in dashed lines to a manageable opening at the bladder neck **112** in solid lines. Bulking agents **140**, such as collagen, PTFE, silicon and fat, are injected beneath the mucosa **113** to narrow the lumen **100** while being monitored by an endoscope **138** as show in Figure 8 using a periurethral injection technique. All of these prior art have significant shortcomings as mentioned in the background.

Several versions of rod-like or tube-like sphincteric closure devices are designed for implantation with a delivery device **107** beneath the surface of mucosa **113** to close the lumen **100** by elevating or lifting the mucosa **113**. Unlike the artificial sphincters requiring manual operation, the rod-like or tube-like sphincteric closure devices allow the urethral **101** muscle to contract and initiate urination. In essence, the sphincteric closure devices specifically assist lumen **100** closure, while minimally interfering with the set of muscles responsible for voiding.

Arch Closure Device

A resilient or elastic arch **151** with a curvature **106** and legs **148**, shown in Figure 9, is implanted beneath the mucosal **113** surface as a sphincteric closure device to shape and assist closure of the urethral lumen **100**. The physical dimensions of the arch **151**, as indicated in Figure 9, are key elements in the sphincteric closure. The tightness and range of lumen closure are related to the elasticity of the arch **151** and the height, H, of the curvature **106**. The length of sphincteric action is related to the length, L, of the arch **151**, the base and shape of the curvature **106**. The width of the sphincteric action is related to the diameter, D, of the arch **151**.

For delivery, the arch **151** is resiliently straightened in a needle **152** with a plunger **153** behind the arch **151**, as depicted in Figure 10. The arch **151** is deployed to resume the pre-disposed curvature **106** by the withdrawal of the needle **152** while the plunger **153** is held stationary, as shown in Figure 11. For lumen **100** closure, the direction of the resumed curvature

106 after deployment is crucial. The cross-sectional shape of the arch **151** and the passage in the needle **152** can be made non-round, elliptical for example, to avoid rotation of the resiliently straightened arch **151** within the needle **152** and to control the direction of deployment. The needle **152** and arch **151** assembly are loaded in a delivery device **107** with an indented pocket or recess **123** and a compressing balloon **127**, as indicated in Figure 12. The cross section of the delivery device **107** is shaped like a semi-circular rod with an inflatable balloon **127** behind the device **107**. Both ends or walls of the indented recess **123** are preferred to be sloped and rounded for gentle insertion into and withdrawal from the urethra **101**. For ease of urethral **101** insertion and withdrawal, the balloon **127** of the delivery device **107** is deflated. When the balloon **127** is inflated within the urethral wall, it pushes the adjacent recess **123** into the soft urethral **101** tissue. Due to the indentation, the mucosal **113** tissue is sheltered from full compression and is loosely packed or less flattened within the recess **123**. The needle **152** carrying the arch **151** passes through an opening in the recess **123** wall, penetrating beneath the surface of the loosely packed mucosa **113** within the recess **123**.

The implantation of the arch **151** involves the following simple steps. Insert the delivery device **107**, as indicated in Figure 12, into the urethra **101**. Inflate the balloon **127**, as shown in Figure 13. Advance the needle **152** housing the arch **151** through the recess **123**, as shown in Figure 14. Deploy the arch **151** by withdrawing the needle **152** while holding the plunger **153** behind the arch **151** stationary, as indicated in Figure 15. Deflate the balloon **127**, as shown in Figure 16. Withdraw the delivery device **107** from the urethra **101**.

Figure 17 depicts the cross section of a urethra **101** with sphincteric deficiency indicated by an open lumen **100** surrounded by mucosa **113**, submucosa **103**, smooth muscle **105** and striated muscle **108**. The delivery device **107** is inserted into the sphincteric region of the urethra **101** as depicted in Figure 18A, with a cross section marked 18B which is depicted in Figure 18B. Figure 18B shows the cross section of the balloon **127** prior to inflation and the panel **122** in the urethra **101**. The balloon **127** is inflated, pushing or positioning the recess **123** against the urethral **101** wall. A plane of mucosa **113** is indicated by a dotted line around the recess **123**, as shown in Figure 19A. Due to the indentation, the mucosal **113** tissue within the recess **123** is loosely packed or less flattened, indicated by the ripple dotted line in front of the indented panel **122** of the recess **123**, while the soft mucosal **113** tissue surrounding the recess **123** is compressed or flattened, also indicated in Figure 19A. Figure 19B depicts a cross section of loosely packed submucosa **103**

against the indented panel **122**, while the surrounding submucosa **103** is compressed and mostly hidden by the inflated balloon **127**. Through a deployment opening **125**, the needle **152** housing the arch **151** is pushed by the needle advancer **154**, penetrating beneath the surface of mucosa **113**, as indicated in Figure 20A, into a receiving opening **126** shown in Figure 14. A cross section of Figure 20A is depicted in Figure 20B, showing the arch **151** in the needle **152** puncturing through the smooth muscle **105** within the recessed region. Even if the needle **152** punctures a blood vessel in the submucosa **103** or smooth muscle **105**, tissue compression by the inflated balloon **127** would greatly minimize bleeding or hematoma.

Although the inflated balloon **127** provides posterior support to the device, the recess **123** portion of the delivery device **107** is preferably made with a rigid material to ensure the needle **152** is properly advanced from the deployment opening **125** to the receiving opening **126**, while the remaining portion is constructed with flexible material to accommodate the curvature of the urethra **101**. To prevent the needle **152** from puncturing the external wall of the urethra **101**, the sharpened tip of the needle **152** is beveled or tapered from the external side to the indented panel **122**, as shown in dotted lines in Figures 12, 13 and 19A. The depth of mucosal **113** penetration by the needle **152** is related to the depth of indentation of the recess **123**, adjustable by the size and/or pressure of the inflated balloon **127**. The thickness of the mucosa **113**, submucosa **103**, and the elasticity of the urethral tissue may also influence the depth of mucosal **113** penetration by the needle **152**.

The arch **151** is then deployed beneath the surface of the mucosa **113** by pulling the needle advancer **154** while holding the plunger holder **155** stationary behind the arch **151**, as depicted in Figure 21A. As the restriction of the needle **152** is released, the arch **151** resumes the pre-disposed curvature **106** beneath the soft urethral **101** tissue, lifting the mucosa **113** toward the lumen **100**, as indicated in Figure 21A. A cross section of Figure 21A is shown in Figure 21B, indicating an elliptical arch **151** lifting smooth muscle **105** and submucosa **103** toward the indented panel **122** of the delivery device. The balloon **127** is then deflated and the deployed arch **151** is separated from the delivery device **107**, as shown in Figure 22A. Figure 22B indicates a cross-sectional view of the deflated balloon **127** and the deployed arch **151** lifting the smooth muscle **105** and submucosa **103** inward. After the delivery device **107** is withdrawn from the urethra **101**, the curvature **106** of the elastic arch **151** elevates the supple mucosa **113**, narrowing or closing the previously opened lumen **100**, as depicted in Figure 23A. Figure 23B shows a cross section of the urethra **101** with a

closed lumen **100** resulting from elevation of the mucosa **113** by the arch **151**.

For stress closure of the lumen **100**, the arch **151** is preferably implanted within the muscle-poor posterior wall **119** to elevate it towards the muscle-rich anterior **118** mucosa **113** for coaptation and closure, as shown in Figure 23A. During stress, such as coughing or sneezing, the urethropelvic ligaments **102** pull on the lateral urethral walls **131** to close the lumen **100**. The arch **151** residing within the posterior wall **119** is unlikely to impede stress closure and probably promotes closure by adding backboard support.

Muscle distribution in the urethra **101** plays a crucial role in sphincteric control, both in closure and voiding. It is likely that voluntary urethral shortening and widening resulting in lumen **100** opening are mainly due to the muscular contraction of the muscle-rich anterior **118** urethral wall and partly by lateral **131** walls. The muscle-poor posterior **119** wall plays only a passive role with minor movement, which would not be significantly affected or irritated by the residing arch **151** during urethral **101** shortening or lengthening for initiating or interrupting urine flow. In fact, injection of bulking agent **140**, as indicated in Figure 8, requires certain injection locations within the urethra **101** in order to take advantage of the muscular distribution in the urethra **101** to gain control of closure and to allow natural voiding.

To treat sphincteric deficiency, injections are selectively filled at the 4 and 8 o'clock positions of the urethral **101** wall, where the urethral anterior **118** wall is at the 12 o'clock position. The bulging agent **140** overlaps at 6 o'clock, the posterior **119** wall position, lifting the posterior **119** half of the mucosa **113** to narrow or close the lumen **100**. Some physicians inject directly into the posterior wall **119**, the 6 o'clock position. To initiate voiding, the muscle-rich anterior wall **118** stiffens and shortens the urethra **101**; at the same time the anterior wall **118** pulls forward, away from the bulging posterior wall **119** to allow the urine **117** to flow through. Similarly, to initiate voiding with an implanted arch **151** in the posterior wall, the anterior wall **118** stiffens and pulls beyond the closing, curving or lifting range of the arch **151**. In essence, to initiate urination, the contraction of the anterior **118** wall widens the lumen **100** beyond the closing range of the arch **151**, as depicted in Figure 24, to allow urine **117** to flow through. After voiding, the muscles relax and the anterior **118** mucosal **113** wall returns within range again to be coapted with the posterior **119** mucosal **113** wall shaped by the arch **104** beneath to prevent unwanted urine leakage.

The depth of the arch **151** delivery is unlike the poorly controlled injection of bulking agent **140** beneath the mucosa **113** as depicted in Figure 8. The amount of bulking agent **140** needed to be visible by the endoscope **138** unpredictably varies from 2 cc to 45 cc. It is quite possible that if the injection is just below the surface of the mucosa **113**, only a small amount of agent **140** is needed to narrow the lumen **100**. However, if the needle **139** is injected deep into the smooth muscle **105** or even into the striated muscle **108**, the outer layer of urethra **101**, a large amount of the agent **140** is likely required to narrow the lumen **100**. The poorly controlled injection technique may be the cause of the unpredictable efficacy, durability, migration and/or immunogenicity of these bulking agents **140**. On the other hand, the depth of arch **151** delivery is controlled by the pre-determined depth of the recess **123** and the size and/or pressure of the balloon **127**. The sphincteric region is estimated by the penetration markers **129** labeled on the delivery device **107** as shown in Figure 25; and the direction of curvature **106** is aligned with the orientation line **130**, also shown in Figure 25, to reproducibly implant a durable and non-immunogenic sphincteric closure arch **151**.

Increasing the diameter of the arch **151** may improve lumen **100** closure by elevating a larger segment of the mucosa **113**. Likewise, delivering two arches **151**, from a double needle delivery device **107** equipped with two deployment openings **125**, as shown in Figure 26, may further improve lumen **100** closure. The cross-sectional view in Figure 27 shows the result using double arches **151** to lift a wide section of mucosa **113** and to fill the lumen **100**.

In an event requiring arch **151** removal, such as infection, non-performance, pain or urine retention, a suture **21** attached to the arch **151** as depicted in Figure 28 can be used as a retrieval device. The suture **21** is preferred to be made with degradable material. The suture **21** linked arch **151** is implanted as mentioned, with a portion of the suture **21** leading to the lumen of the urethra **101**. In the event that arch **151** retrieval is necessary, the suture **21** is pulled to retrieve the arch **151** from the soft and supple urethral **101** tissue. Otherwise, the degradable suture **21** will be cut, voided and/or metabolized.

The long-term stability of the implanted arch **151** is attributable to the design of the arch **151** and the opened space or vacancy created by the lumen **100**. Figure 23A shows a curved arch **151** with legs upon which the curvature **106** pivots. Figure 23B, cross-sectional view of Figure 23A, indicates one leg **148** of the arch **151** pointing above while the other leg **148** points below the page, pivoting the curved portion to lift the soft submucosa **103** and mucosa **113** toward a vacant

space created by the previously open lumen **100**. In essence, the curvature **106** is the pressure point with slight pivotal movement provided by the legs **148**, pressing into an indentation, securely nesting, filling, narrowing and/or closing the vacant gap of the lumen **100**. The compression of the curvature **106** forms a valley or a pocket of soft urethral **101** tissue, indented toward the direction of the lumen **100**, as depicted in Figure 23B. Once the valley of soft urethral **101** tissue is embedded around the curvature **106**, the shifting of the curvature **106** from facing the lumen **100** to sideways should be minimal. Furthermore, the curvature **106** is likely to favor settling into the most supple tissues in the urethra **101**, such as the mucosa **113** and submucosa **103**, which would direct the curvature **106** toward the lumen **100**. Therefore, the direction of the curvature **106** toward the lumen **100** is likely to be the most stable configuration. During voiding, the anterior **118** wall pulls away from the curvature **106**, magnifying the vacant lumen **100**, creating a deepened indentation, which further secures the direction and stability of the sphincteric closure device.

It is also possible to further secure the arch **151** within the urethral **101** wall by additional arch **151** designs. The protruded anchoring devices **149**, as depicted in Figure 29, prevent pivotal swinging of the curvature **106** from facing the lumen **100** to shifting to the side, as well as arch **151** migration. To minimize pivotal swinging of the curvature **106**, the lateral **158** walls of the arch **151** can also be shaped to anchor urethral tissue, as shown in Figure 30A. The cross section of Figure 30A shows the lateral **158** walls for tissue anchoring and the anterior **156** wall for mucosa **113** lifting. The anterior **156** portion of the arch **151**, especially around the pressure point of the curvature **106**, can also be used to anchor urethral **101** tissue to prevent pivotal swinging. Figure 31 depicts a cross section of a curvature **106** of an arch **151**, with an indentation in the anterior **156** side to hold and anchor urethral **101** tissue and to prevent pivotal swinging of the curvature **106**. To minimize device migration with time, tissue ingrowth openings **150** on the sphincteric closure device, as indicated in Figure 32, can be helpful especially in tissue with movement, such as the urethra **101**. The pivotal swinging of the curvature **106** can also be significantly reduced by having a narrow curvature **106** supported with wide legs **148**, as depicted in Figure 33.

Due to the supple texture of the urethra **101**, urine retention from excessive lumen **100** closure or urethral **101** kinking is one of the most common complications in current surgical procedures. An arch **151** is specifically designed to narrow or close the lumen **100** with minimal risk of urethral **101** kinking. The arch **151** is also made with elastic or shape memory material, and a curvature **106** capable of resiliently flattening within the body of the arch **151**, as shown in Figure

34A. As the restriction on the curvature **106** is lifted, the pre-disposed shape of the curvature **106** protrudes out from the body of the arch **151**, as depicted in Figure 34B. The arch **151** can be delivered by the delivery device **107** beneath the surface of mucosa **113** into the urethral **101** wall. The unique function of the arch **151** in Figure 34B is to thicken the soft urethral **101** tissue, narrowing or closing the lumen **100** by lifting the mucosal **113** layer to improve coaptation. The body or the base of the arch **151** also adds support to the urethral **101** wall, eliminating the possibility of urethral **101** kinking.

Instead of delivering the sphincteric closure device with the needle **152**, an arch tube **104** with a passage **144**, legs **148** and curvature **106**, as shown in Figure 35, is designed to be delivered by a trocar **109**. The arch tube **104** is also made with elastic or shape memory material, capable of being resiliently straightened by a relatively rigid trocar **109** sized and configured to fit into the passage **144** of the arch tube, as depicted in Figure 36. To prevent rotation of the arch tube **104** around the trocar **109**, the passage **144** and the cross-sectional shape of the trocar **109** can be made non-round or elliptical.

The implantation of the arch tube **104** involves only the following simple steps: (1) insert the delivery device **107** containing the trocar **109** and the arch tube **104**, as indicated in Figure 37, into the urethra **101**, (2) inflate the balloon **127**, as shown in Figure 38, to press the recess **123** against the urethral tissue, (3) advance the trocar **109** through the recess **123** beneath the surface of the mucosal tissue by pushing the trocar advancer **110**, as shown in Figure 39, (4) slide the arch tube **104** over the trocar **109** by pushing a device advancer **120**, as indicated in Figure 40, and (5) deploy the arch tube **104** within the urethral wall by withdrawing the trocar **109** while holding the device advancer **120** stationary, as depicted in Figure 41, (6) deflate the balloon **127**, and (7) withdraw the delivery device **107** from the urethra **101**. The deployed arch tube **104** is implanted in the urethral **101** wall, elevating the mucosa **113** to close the lumen **100**. A suture **21** attached arch tube **104** is shown in Figure 42. During adverse events, the arch tube **104** can be easily retrieved by pulling on the suture **21**.

The length, width, elasticity, height and shape of the curvature **106** of the arch **151** body or arch tube **104** body play essential roles in the closure of the lumen **100** at rest and in the widening of the lumen **100** during voiding. The length, L, of the arch **151**, **104**, as shown in Figures 9 and 35, should be less than 5 cm, preferably about 1 to 3 cm occupying the sphincteric region of the urethra **101**. The outer diameter, D, should be less than 5 mm, preferably about 0.2 to 2 mm to

elevate mucosa **113** and to close the lumen **100**. The height, H, of the curvature **106** should be less than 5.5 mm, and more likely less than 3.5 mm.

The shape and configurations of the curvature **106** or the pressure points also contribute to sphincteric efficiency. The flat side or the wide side of the elliptical arch tube **104** in Figure 43 is curved toward the lumen **100** to increase the surface area for elevation. The curvature **106** can be lengthened by shortening or eliminating the legs, as indicated in 44, to increase the length of the sphincteric closure and to decrease the pivotal movement of the curvature **106**. It is also possible to have double curvatures **106**, as depicted in Figure 45, to double the convex compression and double the sphincteric actions. The concave side of the arch **151** or **104** can also be oriented toward the lumen **100** to provide compression by the bases of the curvature **106** to close the lumen **100**. Furthermore, by involving both ends or the legs **148**, with the curvature **106**, as indicated in Figure 46, three pressure points generate three sphincteric actions within a small section of the sphincteric region. The stiffness of the curvature **106** can be greatly reduced by connecting two tubular legs **148** to a narrow curved **106** strip, as shown in Figure 47, for gentle lumen **100** closure. Furthermore, the height, H, of the curved **106** strip can be adjusted by the spread of the legs **148**, illustrated in Figure 47. The arch tube **104** can also be composed of modular components to provide selective physical properties, dimension, biodegradative profile, tissue ingrowth, movement or other added benefits. Figure 48 shows a two-pieced arch tube **104**, designed to accommodate potential shortening and lengthening movements at the implant site.

Especially for Types 0, I, IIA and IIB incontinence, merely supporting the posterior **119** urethral wall might be sufficient to correct the incontinent problem. To support the urethral wall, a tube or a rod with adequate rigidity as a backboard support, indicated in Figure 49, can be micro-invasively delivered with the delivery device **107** into the posterior **119** wall, to minimize the withdrawal of the posterior **119** wall during stress.

The muscle-poor posterior urethral wall **119** is the preferred site for implanting the sphincteric closure devices for the following reasons: (1) it provides the backboard support to further gain sphincteric control, (2) the location does not impede stress lumen **100** closure initiated by the tension of urethropelvic ligament **102**, and (3) it frees the muscle-rich anterior wall **118** to widen the lumen **100** to urinate.

Biocompatibility and elasticity of the arch **151** or arch tube **104** are both important to ensure long term success. Nickel titanium, nitinol, has been used in urethral stents with no

evidence of foreign body reactions or corrosion (D. Latal et. al., Urol. Res., 22: 295-300, 1994). The super-elastic property of nickel titanium will allow a curved arch to be resiliently straightened by the needle **152** or the trocar **109**. The shape memory property of the nickel titanium can also provide both curvature and straightening by temperature alteration. Other alloys, such as a stainless steel tempered spring may have the elastic characteristics. Some polymers, such as polypropylene, polyethylene, polyurethane, poly-ether-ketone, DELRIN (acetal resin), polysulfone, polycarbonate, polyimide, polytetrafluoroethylene or others may also be biocompatible and have the elastic modulus to tolerate straightening and mucosal **113** shaping. Especially for testing purposes, a biodegradable arch **151, 104** can be made with poly-lactate, poly-glycolic or other biodegradable materials. All material should be able to withstand sterilization by gamma, electron beam, ETO, steam or other technique to prevent infection.

To improve the performance and/or visibility, the arch **151** or arch tube **104** can be coated with antibiotic, hormone, growth factor, analgesic, blood clotting, nutrient, radiopaque, echogenic, lubricant, swelling, plasma coating and/or other materials.

Swellable Closure Device

Instead of closing the lumen **100** by a curvature **106** of the arch **151, 104**, a swellable closure device **134** can also be delivered with the trocar **109**, as indicated in Figure 50, through a similar delivery device **107**. The swellable closure device **134** is implanted beneath the surface of the mucosa **113**, as depicted in the cross-sectional view in Figure 51, by similar procedures operating the delivery device **107**, as shown in Figures 38 to 41. After absorbing water or serum, the closure device **134** swells and greatly increases in diameter and possibly in length, as indicated in 52. The swellable closure device **134** hydrates and swells within the urethral **101** tissue, pushing the mucosa **113** in toward the vacant space of the opened lumen **100** to narrow and/or close the lumen **100**, as depicted in a urethral **101** cross section in Figure 53.

Collagen, hyaluronate and their derivatives can be processed, dried and sterilized to form a swellable closure device **134**. Hydrophilic polymers, such as polyethylene glycol, can be crosslinked, shaped, dried and sterilized to form a swellable closure device **134**. To improve performance and/or visibility, the swellable device **134** can also be coated or combined with antibiotic, hormone, growth factor, analgesic, blood clotting, nutrient, radiopaque, echogenic, lubricant, and/or other materials.

Inflatable Closure Device

Instead of relying upon swelling to induce lumen **100** closure, an inflatable closure device **135**, as shown in Figure 54, can be folded or rolled tightly in the delivery device **107** to be delivered into the urethral **101** wall. The inflated closure device **135**, depicted in Figure 55, is equipped with a one-way valve **141** in a stem **136** connected to a detachable tube **137** for inflating a chamber of the device **135**. The implantation of the inflatable closure device **135** beneath the mucosa **113** is very similar to the method of delivering the swellable closure device **134**, as indicated in Figure 51. The result of lumen **100** closure is also very similar to the result using the swollen closure device **134**, as depicted in Figure 53. However, one advantage of using the inflatable closure device **135** is that the lumen **100** closure can be adjusted by the amount or the pressure of inflating medium, while the swellable closure device **134** depends on the diameter, depth of implantation and swelling capability. The bag of the inflatable closure device **135** can be made of silicone or polyurethane and inflated with a small amount of inert, viscoelastic and long lasting silicone oil. The inflating medium can also be air, gas or water. To achieve proper lumen **100** closure, the amount of the medium can be monitored by pressure, volume and/or endoscopic observation, as in monitoring bulking agent **140** injections in Figure 8.

Similar to the implanted arch **151**, **104**, the swollen **134** or inflated **135** device also presses into the indentation of the vacant space created by the opened lumen **100**, securely resting within the preferred posterior **119** urethral **101** wall. To initiate voiding, detrusor contraction **147** pushes from the abdomen; the anterior **118** urethral wall stiffens and pulls away from the muscle-poor posterior **119** wall, exceeding the closing range of the swollen **134** or inflated **135** device to enlarge the lumen **100** and to urinate. After voiding, the muscles relax and the anterior **118** mucosal **113** wall is once again within range to be coapted with the posterior **119** mucosal **113** wall, shaped by the swollen **134** or inflated **135** device, to close the lumen **100** and prevent leakage.

The delivery device **107** utilizes a balloon **127** to press or position the recess **123** into the supple mucosa **113** and other soft urethral tissue, allowing the needle **152** or trocar **109** to penetrate beneath the surface of the mucosal **113** layer. The balloon **127** can be replaced by a protruded recess positioner **142**, placed above or below the recess **123** region of the delivery device **107**, as shown in a mid-longitudinal view in Figure 56, ready to be delivered into the urethra **101**. The distal and proximal walls of the protruded recess positioner **142** are sloped, as indicated in Figure 56, for ease of gliding and positioning with the recess **123** of the delivery device **107**.

Compression of the recess **123** into the supple mucosa **113** is achieved by pulling or manipulating the recess positioner handle **143** to align the protruded section of the positioner **142** with the recess **123** region, as shown in Figure 57.

The panel **122** of the delivery device **107** can be made with elastic or shape memory material, forming a curvature to create a recess **123**, as shown in Figure 58, without the balloon **127** or the recess positioner **142**. The elastic panel **122** can be retrieved and resiliently straightened into a panel-restricting tube **159**, as shown in Figure 59. The delivery device **107** with the resiliently straightened panel **122** in a panel-restricting tube **159** is inserted into the urethra **101**, as indicated in Figure 60. The elastic panel **122** resumes the pre-disposed curvature by withdrawing the panel-restricting tube **159**. This causes both ends of the recess **123**, the deployment **125** and receiving **126** openings, to be pressed beneath the surface of the mucosa **113**, as depicted in Figure 61. The arch **151** in the needle **152** is advanced through the recess **123**, tunneling beneath the surface of the mucosa **113**, as indicated in Figure 62. The arch **151** is deployed by withdrawing the needle **152** from the recess **123** while holding the plunger **153** behind the arch **151** stationary as shown in Figure 63. The panel **122** is then retrieved and resiliently straightened in the panel-restricting tube **159** by withdrawing the delivery device **107** while holding the panel-restricting tube **159** stationary, as depicted in Figure 64. To minimize the possibility of scraping or dislocating the deployed arch **151** during the retrieval of the elastic panel **122**, a groove can be indented at the receiving opening **126** to allow the arch **151** to slip through. It is also possible to rotate the delivery device **107** before retrieving the panel **122** into the panel-restricting tube **159** to minimize scraping the deployed arch **151**. As indicated in Figure 64, the deployed arch **151** remains in the urethral **101** wall, lifting the mucosal **113** tissue and closing the lumen **100**.

The resilient panel **122** can be made with nickel titanium alloy for the elastic and/or temperature controlled shape memory capability. Other resilient material, such as spring tempered stainless steel, polypropylene, polyethylene, polyurethane or other polymer, may also be suitable.

Since the urethra **101** is elastic and can be lubricated, it may be feasible to insert a delivery device **107** with a built-in recess **123**, as shown in Figure 65, into the urethra **101**. The distal portion of the delivery device **107** is enlarged to provide the recess **123**. The cross section of the enlarged distal portion of the delivery device **107** can be made elliptical with the deployment opening **125** located at one of the elongated sides, as depicted in Figure 65. During urethral **101** insertion, the urethra **101** conforms to the built-in recess **123**, changing the urethral cross section

from a round to an elliptical configuration, filling the recess **123** with mucosa **113** without causing excessive discomfort from circumferential expansion of the urethra **101**. The delivery device **107** also contains a receiving trough **160** channeled from the recess **123** to the distal end of the delivery device **107**, as shown in Figure 65. The receiving trough **160** can serve as a needle **152** passage and also provide a channel or passage for the arch **151** to minimize scraping or dislocation of the deployed device within the urethral **101** wall during the withdrawal of the delivery device **107**. A similar receiving trough **160** can be used in the delivery device **107**, shown in Figures 18A to 22A, 38 to 41 and 58 to 64, to minimize contact with the deployed lumen closure device during retrieval of the delivery device **107**. The recess **123** of the delivery device **107** can also be created by other means.

Magnetic Closure Device

The outer diameter of the urethra **101** is usually less than 6 mm; the diameters of smooth muscle **105**, submucosa **103** or mucosa **113** are even smaller. Within such short distances, magnetic forces are very strong. A magnet **132** is loaded on a trocar **109**, as indicated in Figure 66. A pair of magnets **132** arranged with polarities attracting each other, as depicted in Figure 67, is delivered one magnet **132** at a time with a similar delivery device **107** into the urethral **101** wall. To facilitate stress closure by the pulling of the urethropelvic ligament **102** upon the lateral **131**walls, the preferred locations of the magnets **132** are within the posterior **119** and anterior **118** walls, sandwiching the lumen **100**, attracting each other to compress and close the lumen **100**, as shown in Figure 68. To void, the anterior **118** muscles stiffen and pull away from the posterior **119** wall, pulling the magnets **132** apart to urinate. After voiding, the muscles relax and the lumen **100** is again compressed and closed by the attraction of two long-lasting magnets **132**.

To improve biocompatibility within the urethra **101**, the magnets **132** can be coated with polytetrafluoroethylene, silicone, polypropylene, polyethylene, polyurethane, poly-ether-ketone, DELRIN (acetal resin), polysulfone, polycarbonate, polyimide or other coating materials. For visibility, echogenic, radiopaque or other types of coatings can be used.

To ensure proper alignment of two attracting magnets **132**, two delivery devices **107** loaded with magnets **132** are inserted into the urethra **101**, as indicated in Figure 69, above and below each other with the recesses **123** facing opposite directions. As both recesses **123** align back to back within the urethra **101**, as indicated in Figure 70, the cross section of the aligned recesses **123** greatly increases in diameter, pressing both indented recesses **123** into the soft

mucosa **113**. This allows both trocars **109** to penetrate and deliver the magnets **132** beneath the surface of mucosa **113**, directly across the lumen **100** from each other, as shown in Figure 70.

Similar to the arch **151, 104** attached to a suture **21**, the magnets **132** or the swellable device **134** can also be attached to a suture **21** for device retrieval, as shown in Figure 71.

Multiple devices **151, 104, 134, 135, 132** utilize the needle **152** or trocar **109** to deliver implants beneath the mucosa **113**. It is also possible to implant some of the devices **134, 132** without the needle **152** or trocar **109**, by covering the devices **134, 132** with a coating **133**, shaped to penetrate the mucosa **113**, as shown in Figure 72. The coating **133** is preferably biodegradable, such as poly-lactate, poly-glycolic or other biodegradable material. After the device **134, 132** has been delivered, the coating **133** degrades and the sharp feature erodes for a safe and effective implant.

Benefits of the Sphincteric Closure Devices

The device **151, 104, 134, 135** or **132** previously discussed is designed to narrow and/or close the lumen **100** to treat Types 0, I, II and III urinary incontinence, using micro-invasive techniques with the delivery device **107**. The device **151, 104, 134, 135** or **132** can also provide the backboard support to the posterior **119** wall to increase urethral resistance, similar to the surgical vaginal **114** repositioning or sling procedure. But unlike invasive surgical procedures, the device **151, 104, 134, 135** or **132** is micro-invasively implanted in the urethral **101** wall, without involving the vagina **114**; therefore it is applicable to both men and childbearing women. Furthermore, the range or intensity of lumen **100** closure by the device **151, 104, 134, 135** or **132** is predetermined, measured and limited to avoid urine retention, the most common and unpredictable complication from excessive suture **21** tightening in current surgical procedures.

Similar to the filling location of the bulking agent **140** injection, the preferred device **151, 104, 134** or **135** location is within the posterior wall **119** to allow the muscle-rich anterior **118** wall to widen, control and initiate urination. However, unlike the bulking agents **140**, the device **151, 104, 134** or **135** is too large to disperse, too inert to degrade and is accurately delivered to avoid repeating painful injections.

Both the prior art artificial sphincters and the sphinteric closure device **151, 104, 134, 135** or **132** are designed to close the lumen **100** for treating Type III urinary incontinence. However, the insertion of existing artificial sphincters is very invasive, with numerous common complications, such as tube kinking, bladder neck necrosis and infection. Furthermore, the prior

art artificial sphincter is manually operated, while the device **151, 104, 134, 135** or **132** in this invention allows the urethral **101** muscles to control urination and assists with lumen **100** closure. Due to the significant size and location of the prior art artificial sphincters, simple activities, such as sitting or bike riding, should be minimized. The micro-artificial sphincteric device **151, 104, 134, 135** or **132** is unlikely to be impacted by daily routines.

Another fine distinction between the implantation of the sphincteric closure device beneath the surface of mucosa **113** and the current surgical corrections is that the device **151, 104, 134, 135** or **132** operates at the sphincteric level, not from outside of the urethral **101** wall. Therefore, the device **151, 104, 134, 135** or **132** is capable of achieving much greater precision, reproducibility and control.

Micro-invasive procedures usually translate into significantly lower costs, shorter recovery times and far fewer complications. Furthermore, the micro-invasive, mini-sphincteric closure device **151, 104, 134, 135** or **132** is suitable for men, older women, and childbearing women, as well as weak patients with minimal to no activity restrictions.

Opening Urethral Obstruction

The supple texture of smooth muscle **105** and the compliant nature of the urethral **101** wall are crucial elements for successful urethral **101** closure during stress. The compliant urethra **101** is not made to resist external compression or ingrowth of surrounding tissue, such as benign prostatic hyperplasia (BPH). As the prostate **124** grows with time, the urethra **101** is squeezed and the lumen **100** is pinched or even closed, as depicted in Figure 73.

The polarities of the previously discussed magnets **132** were arranged for attraction, assisting lumen **100** closure in a deficient urethral sphincter. By reversing the magnetic polarities from attracting to repelling, two or more repelling magnets **132** implanted by the delivery device **107** serve to open the pinched lumen **100** by repelling and pushing against the impinging prostatic **124** tissue, as shown in Figure 74.

In addition to opening the impinged lumen **100** with a micro-invasive procedure, the magnetic devices **132** can be coated or loaded with iodide 125, iodide 131, or other radioactive or chemotherapeutic agent to treat malignant growth in the prostate **124.**

Unlike the urethral stents, which are susceptible to clotting by mucosal **113** ingrowth, the magnets **132** are micro-invasively implanted beneath the mucosa **113**, unaffected by the fast growing tissue. The close proximity of these magnets provides strong magnetic forces to repel the

urethral **101** tissue and to widen the lumen **100**. As long as the magnets **132** are properly anchored, the magnetic field will likely provide long-lasting urethral **101** clearance, allowing the urine **117** to flow freely.

To further secure the magnets **132** within the urethral **101** wall, anchoring devices **149** or tissue ingrowth openings **150** can also be added to secure the magnetic **132** device, as depicted in Figure 75. The anchoring devices **149** can be made with degradable material, allowing time for tissue ingrowth to secure the device **132** before degradation.

Medical Alert Tags

Most of the devices in this invention are designed to increase urethral resistance by narrowing and/or closing the lumen **100**. In hospitals, health care professionals often insert catheters into the urethra **101** for draining. It is possible that the insertion of catheters, especially 12 French or larger, can injure the urethra **101**. If the patient has a device **151, 104, 134, 135** or **132**, a medical alert tag should be worn.

Overall Device and Method

Due to the functional similarities of several parts in the delivery devices **107**, the names of these parts can be consolidated into generic names. The needle **152** and the trocar **109** can be generally called a trocar or a puncture device. The needle advancer **154** for operating the needle **152** and the trocar advancer **110** for operating the trocar **109** can be generally called a puncture device advancer. The plunger holder **155** and the device advancer **120** can be generally called an implant advancer. The balloon **127** and the recess positioner **142** on the delivery device **107** can be generally called a compressing member. The panel-restricting tube **159** can be generally called a panel deployment delivery device.

The sphincteric closure devices, arch **151**, arch tube **104**, swellable device **134**, inflatable device **135** and magnetic device **132** are all implants. Therefore, the device **151, 104, 134, 135** or **132** can also be called the implant. The main functions of the implants are to treat urinary dysfunctions by altering, reshaping, supporting, restructuring or deforming the urethral tissue.

The methods for delivering the arch **151** with the needle **152** and the arch tube **104** with the trocar **109** are described in detail. By changing the sizes and configurations, the swellable closure device **134**, the inflatable device **135** and the magnetic device **132** can also be implanted in the urethral **101** wall with the delivery device **107** using the needle **152** with the plunger **153**, or the trocar **109** with the device advancer **120**. Multiple devices **151, 104, 134, 135** and/or **132** can also

be implanted in series or side by side, using the same or mixed types of devices within a urethra **101**.

It is also to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also comprises any other modification, changes or equivalents within the scope of the claims. Many features have been listed with particular configurations, options, and embodiments. Any one or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments.

It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues, surgical sites, human or animals, are not the only uses for which the invention may be used. Different materials, shapes, constructions or designs for the arch **104**, swellable closure device **134**, inflatable closure device **135**, magnetic device **132**, delivery device **107** and/or recess positioner **142** can be substituted and used. Different methods for delivering the device **151**, **104**, **134**, **135** or **132** can also be modified.

The use of the delivery device **107** is also foreseen for injecting bulking agents **140** accurately into the urethral **101** wall, or narrowing the pylorus or intestine to delay stomach emptying for weight loss purposes. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims.

We claim:

1. A urethral implant for implantation into a urethral wall for treatment of incontinence, said urethral implant comprising:

an elongated body formed of a resilient material, said body having a first position and a second position, said first position having a curved configuration, said second position being straighten from said first position such that said elongated body is implantable using an implant delivery device,

wherein when said elongated body is placed within a urethral wall, said elongated body is capable of reshaping the urethral wall and thereby facilitating closure of the urethra.

2. The urethral implant of claim 1 wherein said urethral implant has a plurality of curvatures.

3. The urethral implant of claim 1 further comprising a suture connected to an end of said elongated body.

4. The urethral implant of claim 1 wherein said urethral implant has anchoring elements extending from the surface thereof.

5. The urethral implant of claim 1 wherein said urethral implant is formed of a plurality of modular parts.

6. The urethral implant of claim 1 wherein said urethral implant has a circular cross section.

7. The urethral implant of claim 1 wherein said urethral implant has an oval cross section.

8. The urethral implant of claim 1 wherein said urethral implant has an irregular cross section.

9. The urethral implant of claim 1 wherein said urethral implant is formed at least partially of a shape memory material.

10. The urethral implant of claim 1 wherein said urethral implant is formed of a hollow tubular member.

11. The urethral implant of claim 1 wherein said urethral implant is solid.

12. The urethral implant of claim 1 wherein said elongated body is connected to a base member.

13. The urethral implant of claim 12 wherein, in said second position, said base member forms a perimeter around said elongated body.

14. The urethral implant of claim 12 wherein said elongated body is cut out from said base member.

15. The urethral implant of claim 12 wherein, in said first position, said curved configuration of said elongated body protrudes from said base member.

16. The urethral implant of claim 1 wherein said elongated body has a plurality of tissue in-growth holes.

17. The urethral implant of claim 1 wherein said implant is configured such that, when implanted in an operative position within a patient's urethra, said implant is orient such that a longitudinal axis of said implant is aligned with the longitudinal axis of the urethra and a convex side of said implant faces the urethral lumen.

18. The urethral implant of claim 1 further comprising means for orienting said implant with a convex side of said curved configuration oriented toward the urethral lumen.

19. A urethral implant delivery system, comprising:
an implant delivery device, including:
an elongated tubular member having a first end and a second end,
a panel having a front surface and a back surface,
an endwall connecting said panel to said elongated tubular member, said front surface and said endwall forming a recess,
a trocar at least partially extendable into said recess,
a handle connected with said second end of said tubular member,
and a urethral implant sized and configured to fit within said tubular member.

20. The urethral implant delivery system of claim 19 further comprising a deployment opening in said endwall and said trocar extends into said recess through said deployment opening.

21. The urethral implant delivery system of claim 19 further comprising an inflatable balloon located adjacent to said back surface of said panel.

22. The urethral implant delivery system of claim 19 wherein said implant delivery device further comprises a second endwall extending from said panel.

23. The urethral implant delivery system of claim 22 wherein said second endwall has a receiving opening.

24. The urethral implant delivery system of claim 19 wherein said urethral implant has a resilient curve.

25. The urethral implant delivery system of claim 24 wherein said urethral implant is formed of a shape memory material.

26. The urethral implant delivery system of claim 24 wherein said urethral implant is formed of a nickel titanium alloy.

27. The urethral implant delivery system of claim 24 wherein said urethral implant is formed of spring tempered stainless steel.

28. The urethral implant delivery system of claim 24 wherein said urethral implant is less than 5 centimeters in length.

29. The urethral implant delivery system of claim 24 wherein said urethral implant further comprises a leg portion extending from each end of said resilient curve.

30. The urethral implant delivery system of claim 29 wherein said leg portions are generally straight.

31. The urethral implant delivery system of claim 24 wherein said urethral implant is formed from a plurality of modular parts.

32. The urethral implant delivery system of claim 24 wherein said urethral implant is hollow.

33. The urethral implant delivery system of claim 32 wherein said urethral implant has a non-round passage extending therethrough.

34. The urethral implant delivery system of claim 24 further comprising a suture attached to said urethral implant.

35. The urethral implant delivery system of claim 24 wherein said urethral implant is formed from a material chosen from the group consisting of polypropylene, polyethylene, polyurethane, poly-ether-ketone, DELRIN (acetal resin), polysulfone, polycarbonate, polyimide, polytetrafluoroethylene, poly-lactate and poly-glycolic.

36. The urethral implant delivery system of claim 24 wherein said urethral implant has a coating chosen from the group consisting of antibiotic, hormone, growth factor, analgesic, blood clotting, nutrient, radiopaque, echogenic, lubricious, swelling and plasma coatings.

37. The urethral implant delivery system of claim 19 wherein said urethral implant has a plurality of curves.

38. The urethral implant delivery system of claim 19 wherein said urethral implant is swellable.

39. The urethral implant delivery system of claim 38 wherein said urethral implant is formed of a material chosen from the group of materials consisting of collagen, hyaluronate and polyethylene glycol.

40. The urethral implant delivery system of claim 38 wherein said urethral implant has a coating chosen from the group of coatings consisting of antibiotic, hormone, growth factor, analgesic, blood clotting, nutrient, radiopaque, echogenic and lubricious coatings.

41. The urethral implant delivery system of claim 19 wherein said urethral implant has a chamber located therein and is inflatable.

42. The urethral implant delivery system of claim 41 wherein said urethral implant has a one-way valve extending into said chamber for inflation thereof.

43. The urethral implant delivery system of claim 41 wherein said urethral implant is inflatable with a material chosen from the group of materials consisting of silicone oil, air, gas and water.

44. The urethral implant delivery system of claim 41 wherein said urethral implant is formed of an elastic material.

45. The urethral implant delivery system of claim 41 wherein said urethral implant is foldable to allow said implant to fit within a delivery lumen.

46. The urethral implant delivery system of claim 41 wherein said urethral implant is formed from a material chosen from the group of materials consisting of silicon and polyurethane.

47. The urethral implant delivery system of claim 19 wherein said urethral implant has magnetic properties and further comprising a second magnetic implant.

48. The urethral implant delivery system of claim 47 wherein said magnetic urethral implants further comprising a suture.

49. The urethral implant delivery system of claim 47 wherein said magnetic urethral implants further comprising an anchoring device.

50. The urethral implant delivery system of claim 47 wherein said magnetic urethral implants further comprising a tissue ingrowth opening.

51. The urethral implant delivery system of claim 47 wherein said magnetic implants have opposite poles on first ends thereof, whereby the implants attract one another.

52. The urethral implant delivery system of claim 47 wherein said magnetic implants have like poles on first ends thereof, whereby the implants repel one another.

53. The urethral implant delivery system of claim 47 wherein said implant has a coating chosen from the group consisting of polytetrafluoroethylene, silicone, polypropylene, polyethylene, polyurethane, poly-ether-ketone, DELRIN (acetal resin), polysulfone, polycarbonate, polyimide, echogenic, radiopaque material, poly-lactate, poly-glycolic, iodide 125, iodide 131, radioactive material and chemotherapeutic agent.

54. The urethral implant delivery system of claim 19 wherein said trocar has a sharp tip.

55. The urethral implant delivery system of claim 54 wherein said trocar is beveled such that said sharp tip is adjacent said panel.

56. The urethral implant delivery system of claim 19 wherein said trocar has a passage extending therethrough, said passage being sized and configured to contain at least one of said urethral implant.

57. The urethral implant delivery system of claim 56 further comprising an implant advancer located at least partially within said trocar.

58. The urethral implant delivery system of claim 56 wherein said passage is non-round.

59. The urethral implant delivery system of claim 54 wherein said trocar is sized and configured to pass through a passage extending through said urethral implant.

60. The urethral implant delivery system of claim 59 further comprising a urethral implant advancer located around said trocar.

61. The urethral implant delivery system of claim 59 wherein the cross section of said trocar is non-round.

62. The urethral implant delivery system of claim 19 wherein said tubular member has at least one orientation line visible on a surface thereof.

63. The urethral implant delivery system of claim 19 wherein said tubular member has at least one penetration marker visible on a surface thereof.

64. The urethral implant delivery system of claim 19 further comprising a compressing member located adjacent to said back surface of said panel.

65. The urethral implant delivery system of claim 64 wherein said compressing member is sized and configured to be locatable adjacent to said back surface of said panel and to compress the mucosa.

66. The urethral implant delivery system of claim 19 further comprising a second endwall attached to a distal end of said panel, said second endwall having a receiving trough located therein.

67. A urethral implant delivery system, comprising:

a delivery device including:

an elongated tubular member having a first end and a second end,
a panel having a first end portion connecting said panel to said elongated tubular member,
said panel having a first position and a second position, said first position having a curved configuration forming a recess, said second position being straightened from said first position,
and a trocar at least partially extendable into said recess,
and a urethral implant sized and configured to fit within said tubular member.

68. The urethral implant delivery system of claim 67 wherein said panel has a receiving opening in a second end portion thereof.

69. The urethral implant delivery system of claim 68 wherein said receiving opening is a generally round hole extending into said second end portion of said panel.

70. The urethral implant delivery system of claim 68 wherein said receiving opening is a trough extending through said second end portion of said panel.

71. The urethral implant delivery system of claim 67 wherein said panel is formed of a resilient material.

72. The urethral implant delivery system of claim 67 wherein said panel is formed of a shape memory material.

73. The urethral implant delivery system of claim 67 wherein said panel is formed of a material chosen from the group consisting of nickel titanium alloy, spring tempered stainless steel, polypropylene, polyethylene and polyurethane.

74. The urethral implant delivery system of claim 67 further comprising a deployment opening in said first end portion.

75. The urethral implant delivery system of claim 67 further comprising a deployment delivery device located at least partially around said delivery device.

76. The urethral implant delivery system of claim 75 wherein said panel is moved from said second position to said first position by said deployment delivery device.

77. The urethral implant delivery system of claim 67 wherein said panel is moved from said second position to said first position by a change in temperature.

78. A method of micro-invasively treating a dysfunction of the urinary tract, the method comprising the steps of:

(a) inserting an implant delivery device into the urethra of a patient;
(b) orienting a recess of said implant delivery device adjacent to tissue at a first location;
(c) pressing said recess against the tissue, thereby causing a portion of the tissue to enter said recess;
(d) deploying a trocar into said recess;
(e) deploying an implant within a urethral wall located within said recess;
(f) retracting said trocar;
(g) and removing said implant delivery device, leaving said implant within the urethral wall.

79. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein step (c) is accomplished by inflating a balloon located adjacent to a back surface of said implant delivery device.

80. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein step (c) is accomplished by positioning a tissue compressor adjacent to a back side of said implant delivery device.

81. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein step (c) is accomplished by allowing a resilient panel to form a curved configuration to create said recess.

82. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein step (f) allows said implant to resiliently return to a curved configuration, thereby promoting closure of the urethral passage.

83. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein said implant is delivered beneath the mucosa.

84. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein said implant is delivered to a posterior wall of the urethra.

85. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78, further comprising the step of:

(h) allowing said implant to swell, thereby closing the urethral passage.

86. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78, further comprising the step of:

(h) inflating said implant, thereby closing the urethral passage.

87. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein steps (c) through (f) are repeated at a second location within the urethra.

88. The method of micro-invasively treating a dysfunction of the urinary tract of claim 87 wherein said second location is across the urethral lumen from said first location.

89. The method of micro-invasively treating a dysfunction of the urinary tract of claim 88, further comprising the step of:

(h) allowing a magnetic attraction between said implants at said first and second locations to close the urethral passage.

90. The method of micro-invasively treating a dysfunction of the urinary tract of claim 88, further comprising the step of:

(h) allowing a magnetic repelling force between said implants at said first and second locations to open the urethral passage.

91. The method of micro-invasively treating a dysfunction of the urinary tract of claim 78 wherein steps (b) through (f) are repeated at second, third and fourth locations within the urethra.

92. The method of micro-invasively treating a dysfunction of the urinary tract of claim 91, further comprising the step of:

(h) allowing magnetic repelling force between said implants to open the urethral passage.

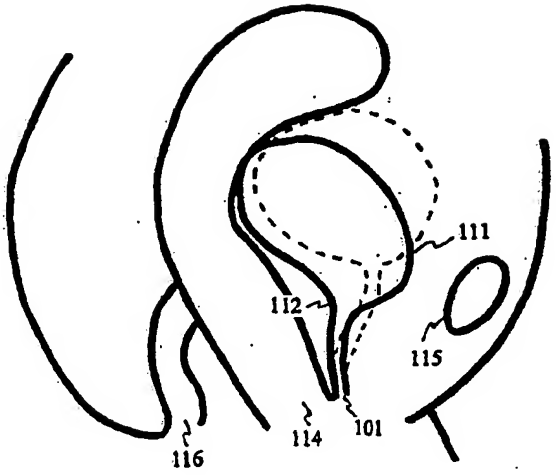


Figure 1

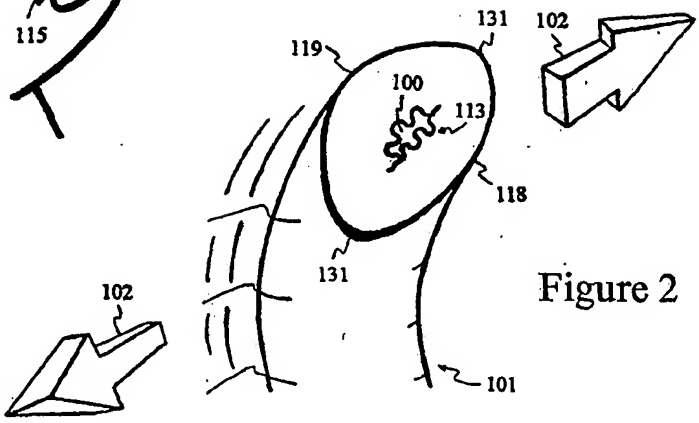
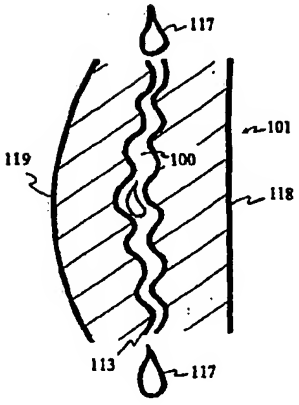


Figure 2



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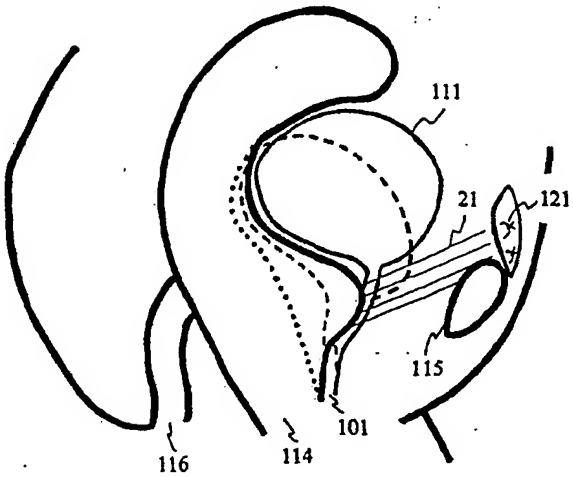


Figure 4
Prior Art

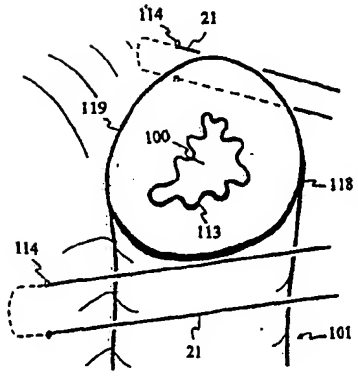


Figure 5
Prior Art

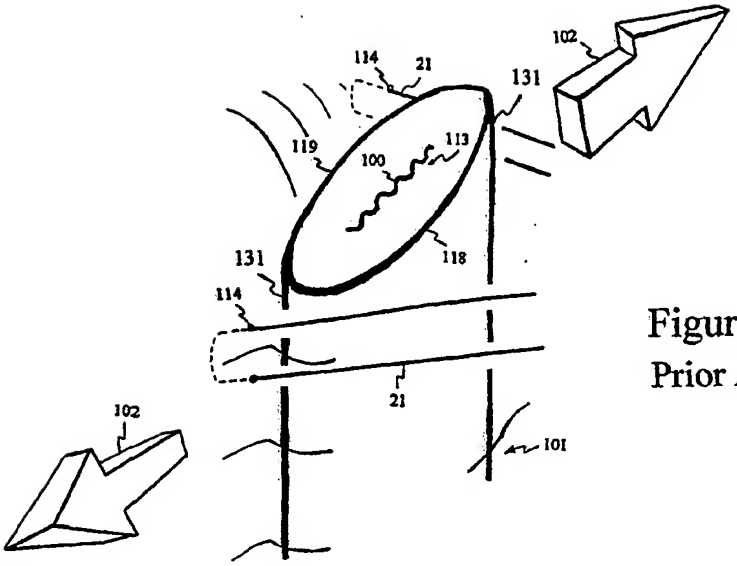


Figure 6
Prior Art

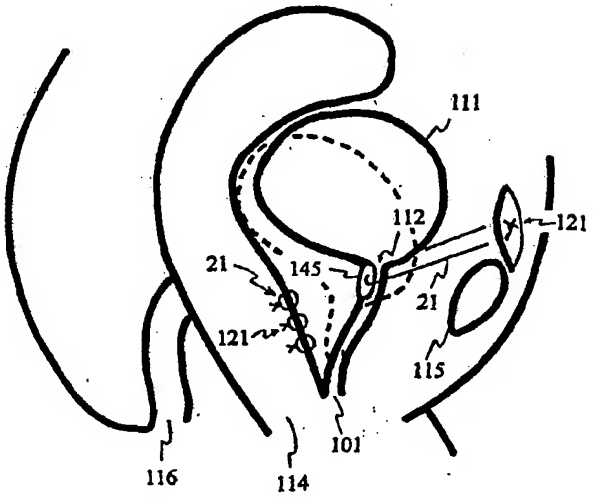


Figure 7
Prior Art

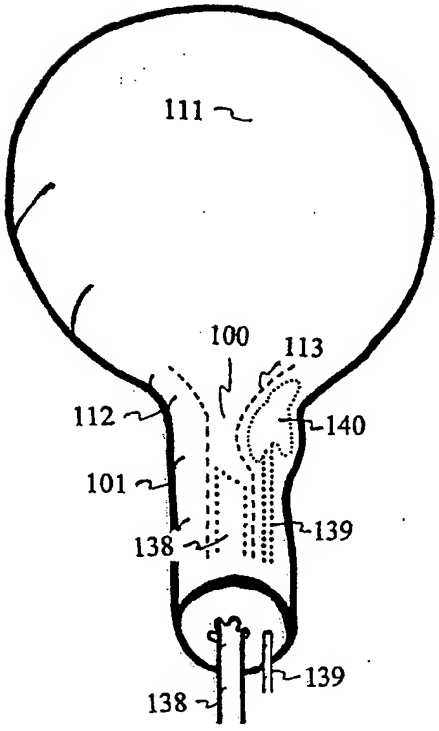
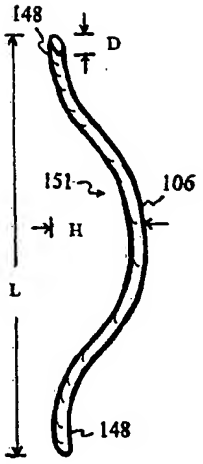


Figure 8
Prior Art



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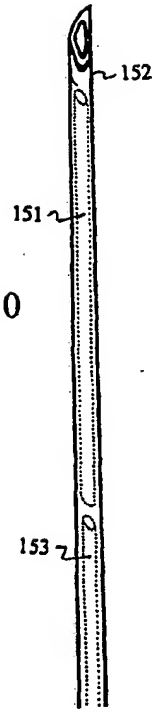

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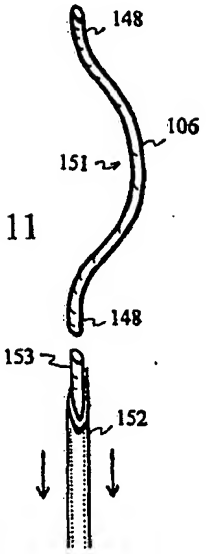

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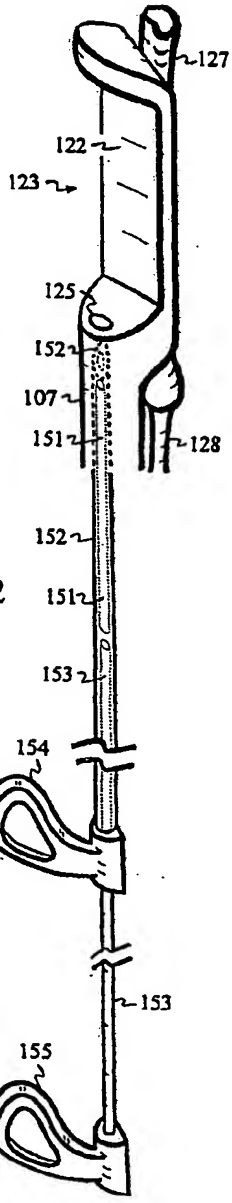

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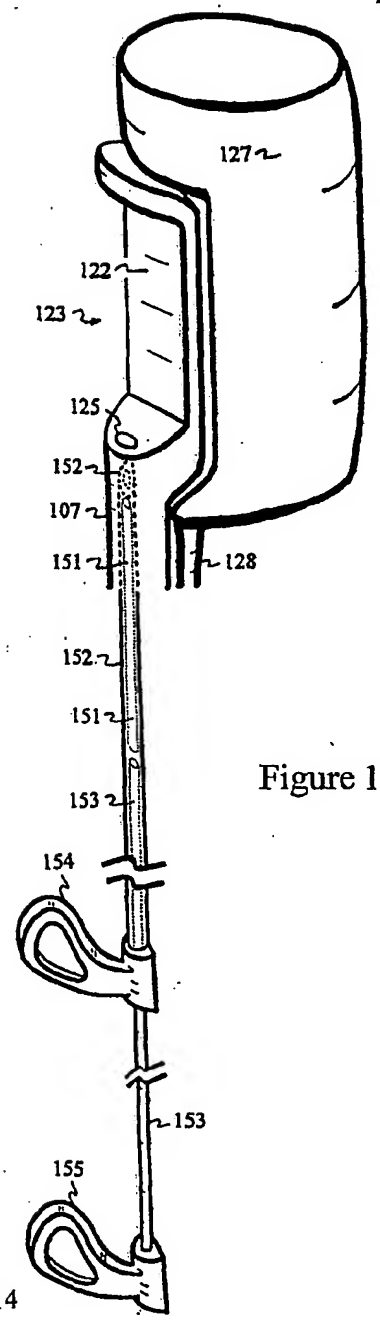

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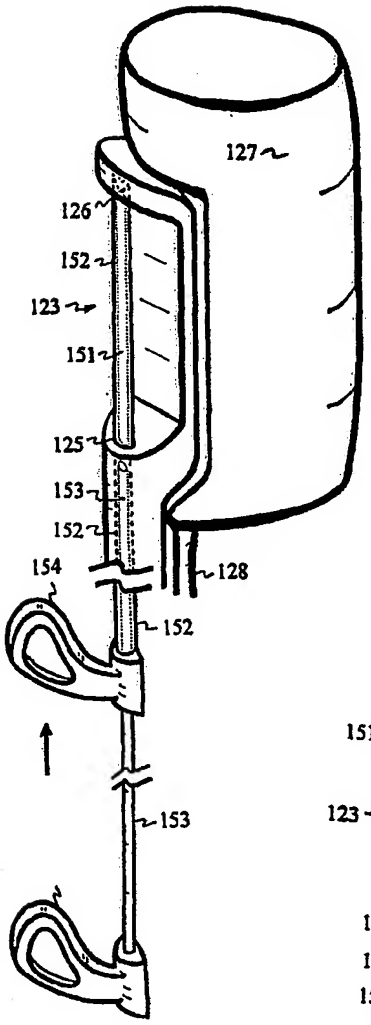

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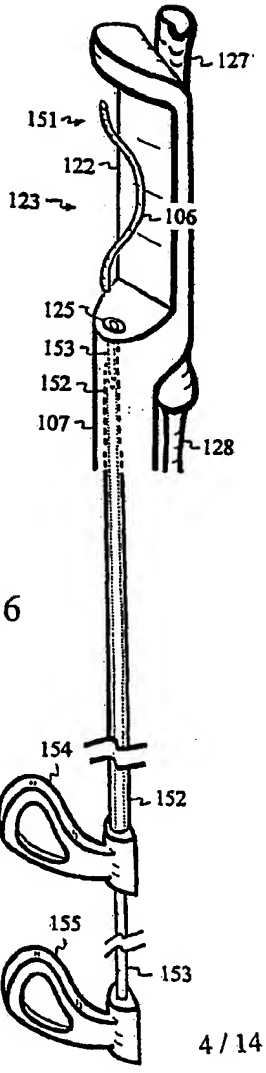

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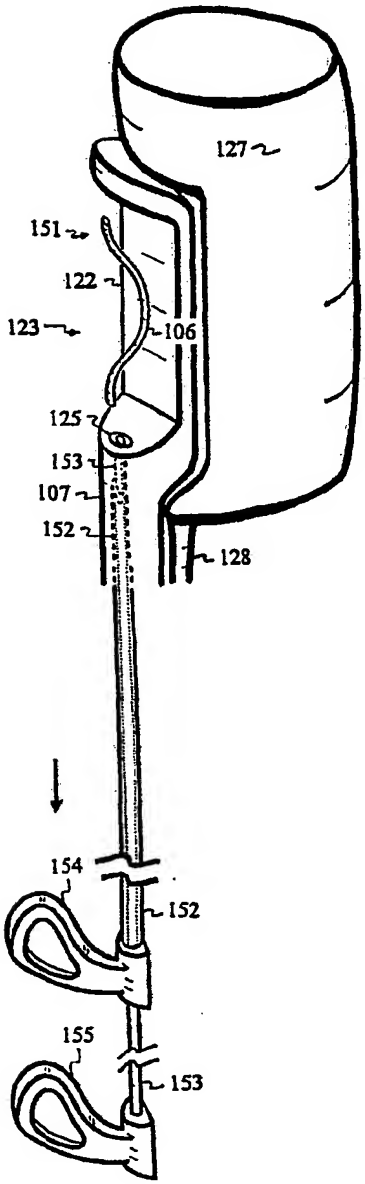

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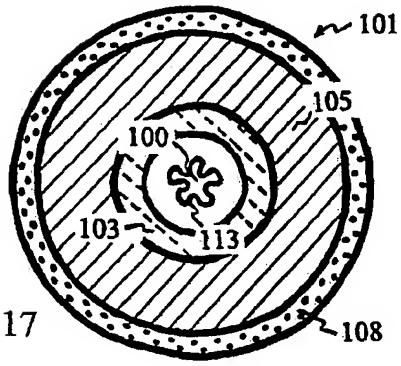

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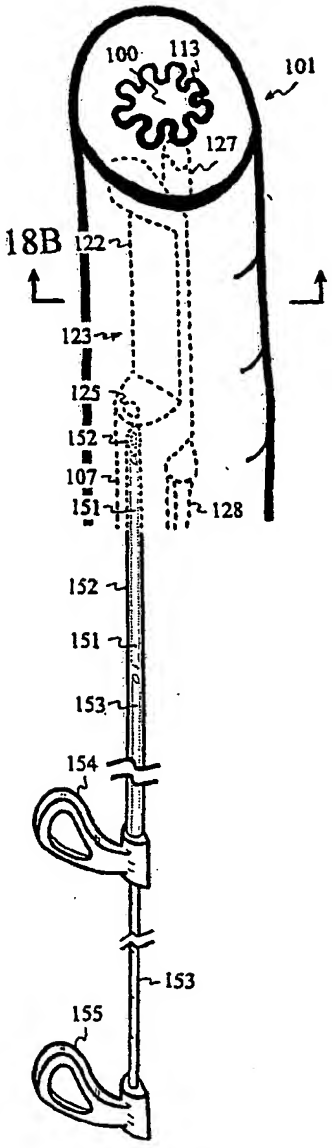


Figure 18A

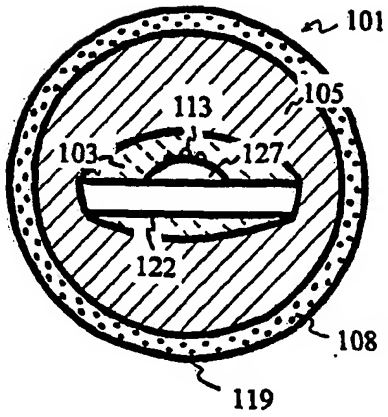


Figure 18B

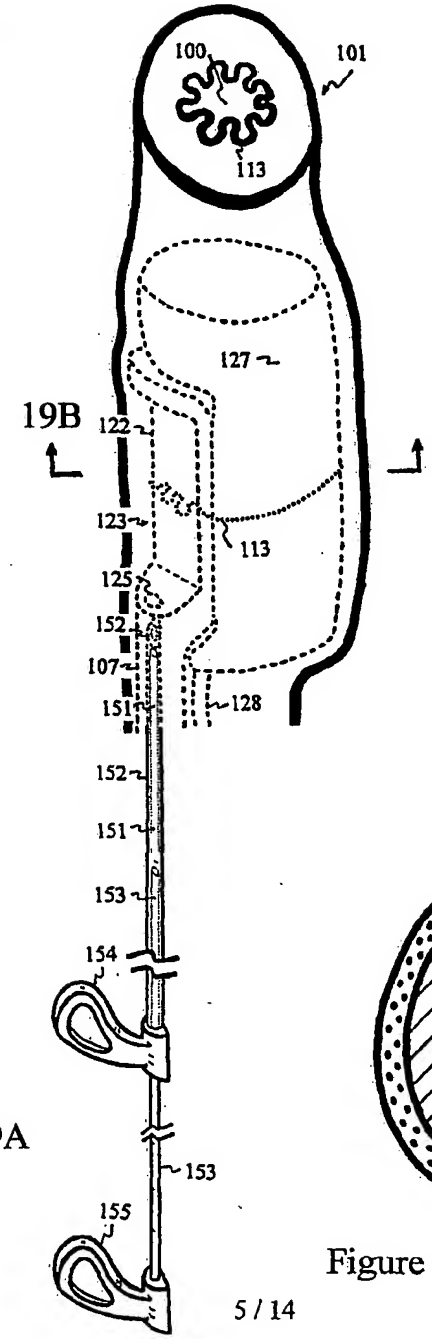
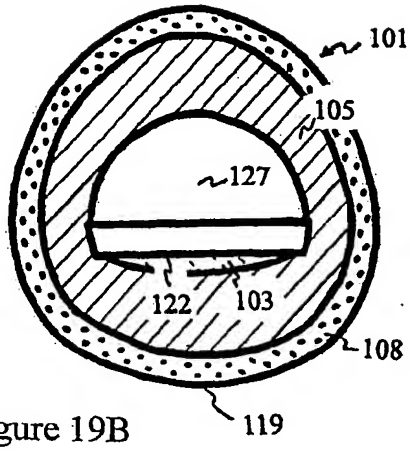


Figure 19A



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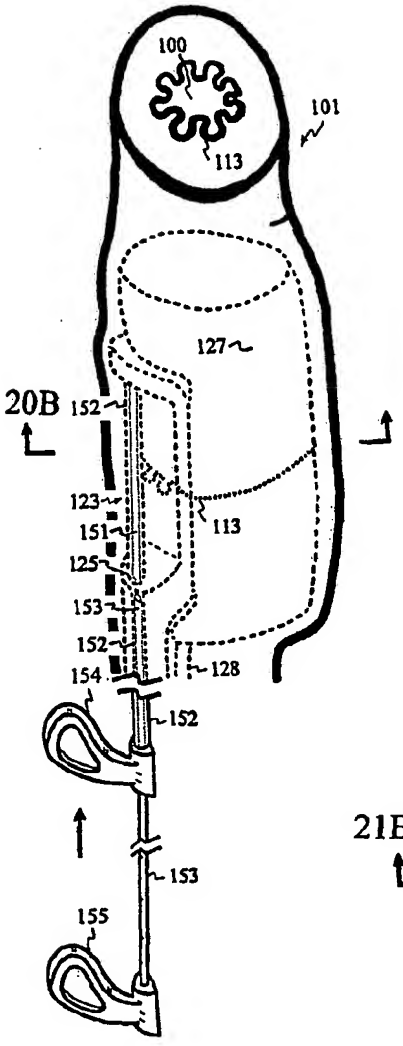
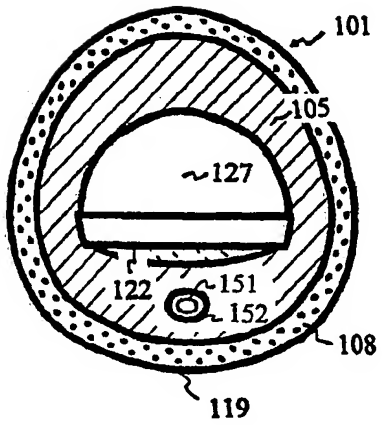


Figure 20A



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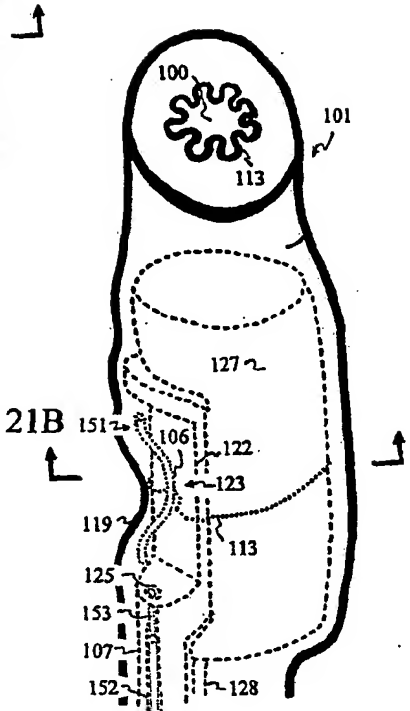

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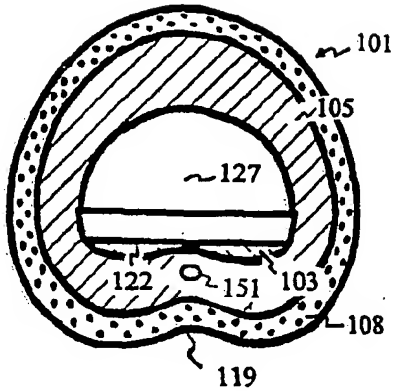

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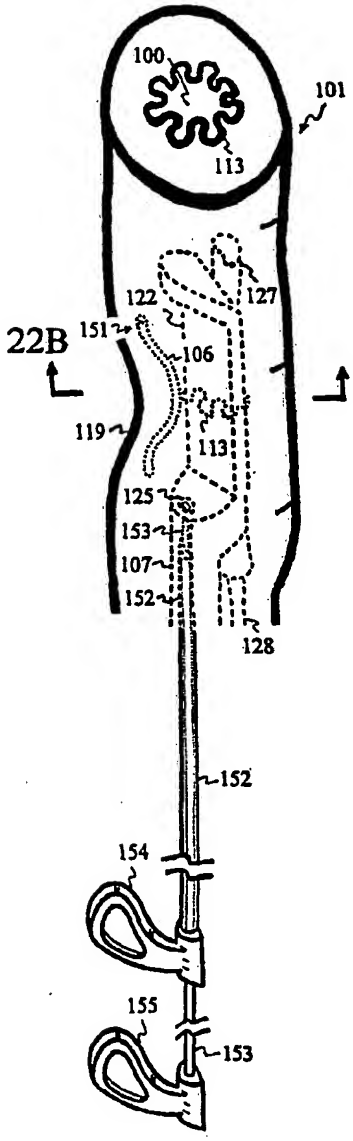
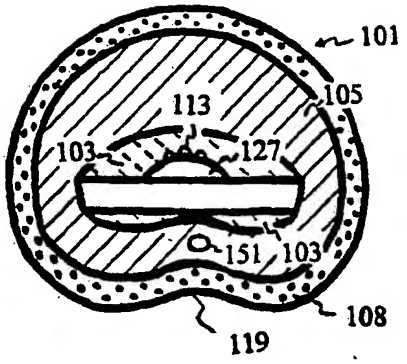
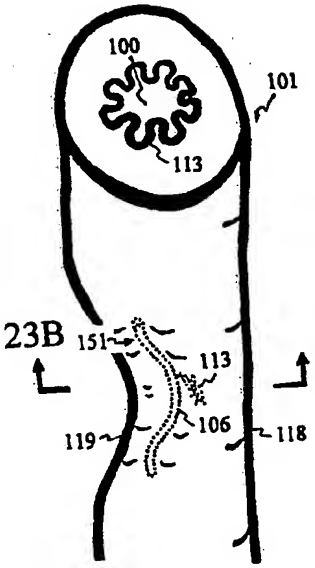


Figure 22A

Figure 22B





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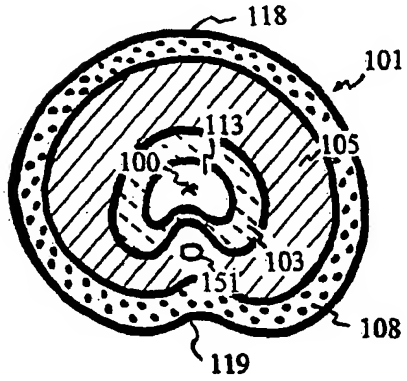

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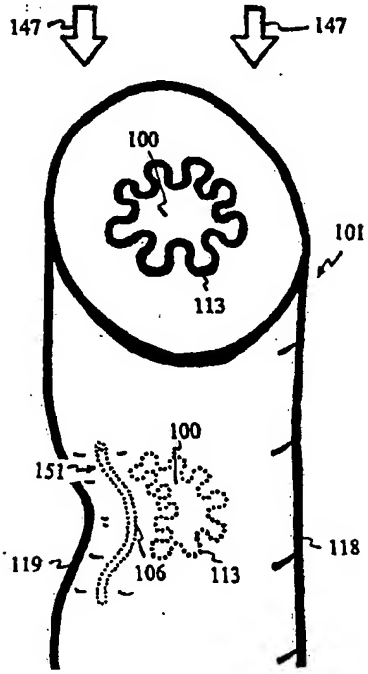

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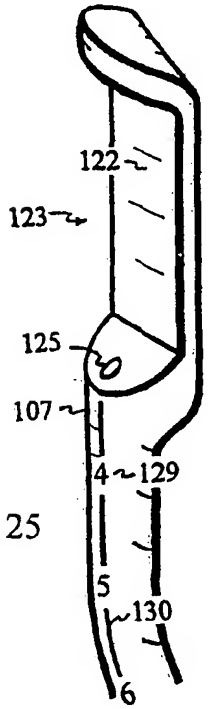

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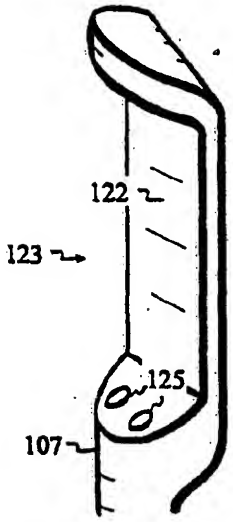

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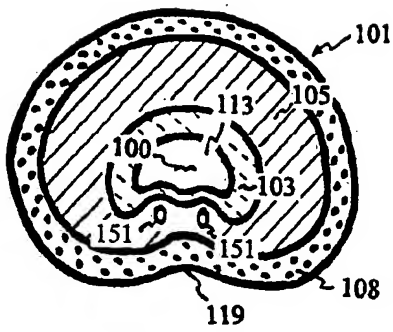

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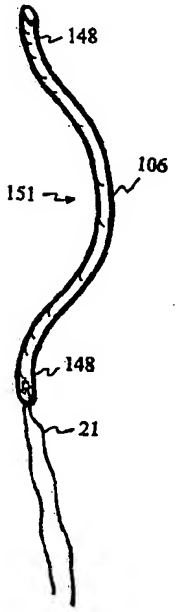

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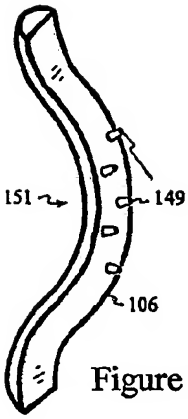

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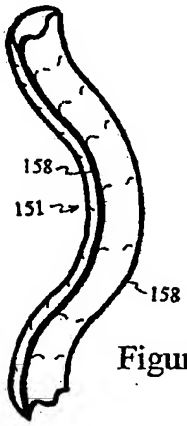

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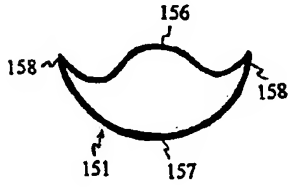
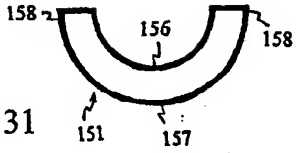


Figure 30 B



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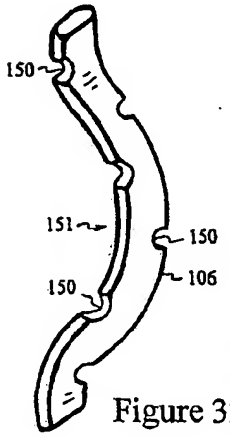

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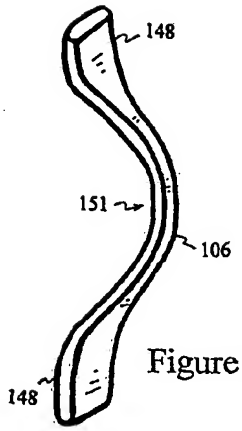

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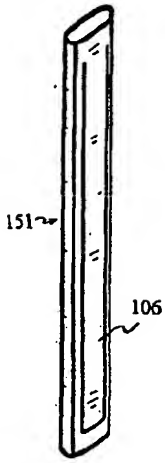

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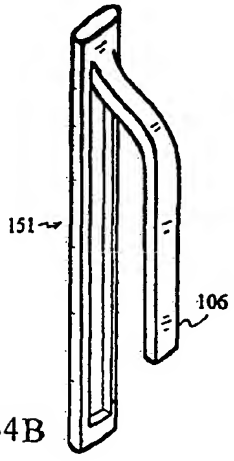

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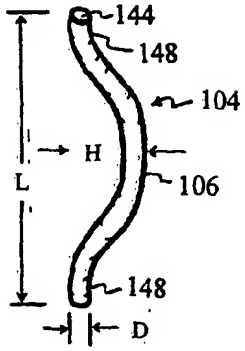

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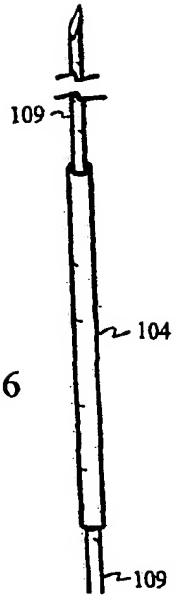

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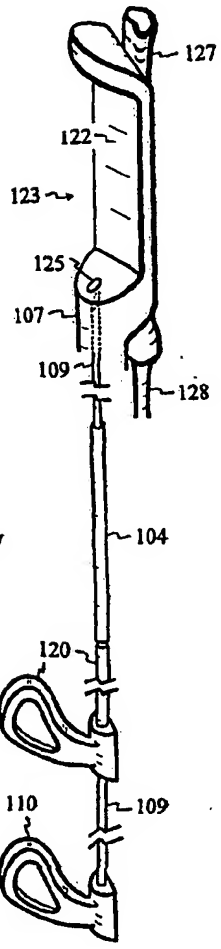

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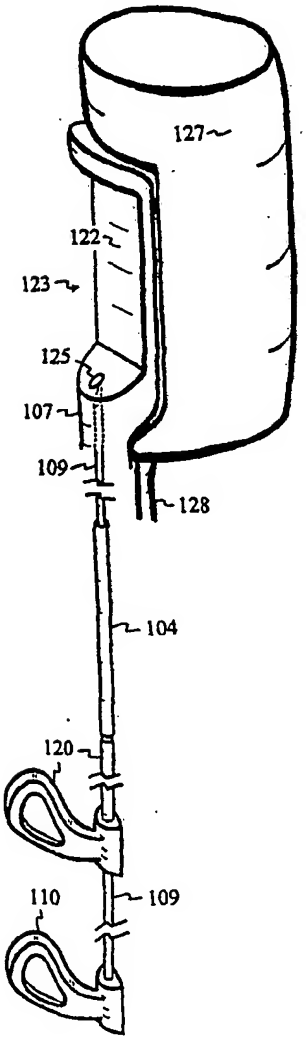

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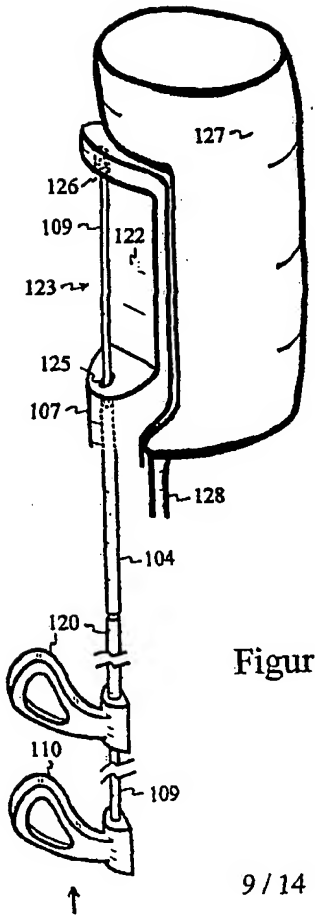

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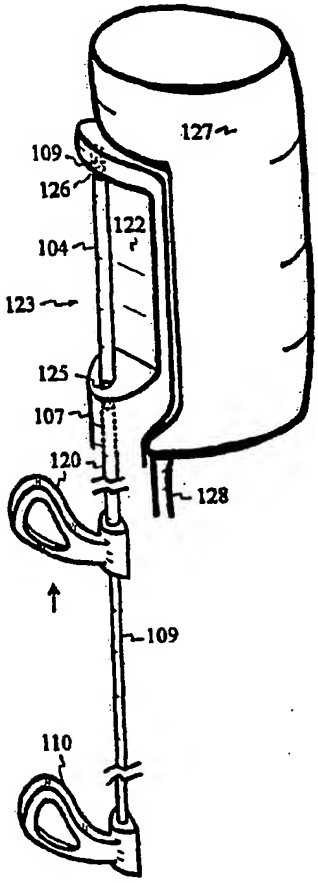

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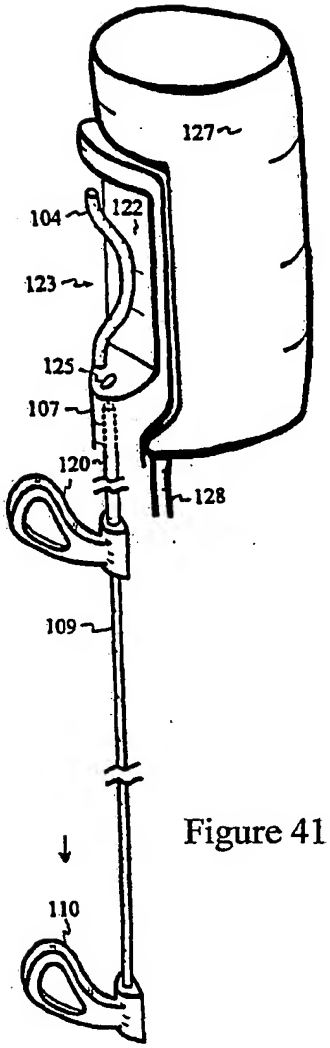

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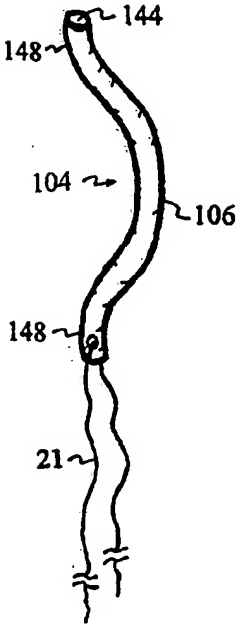

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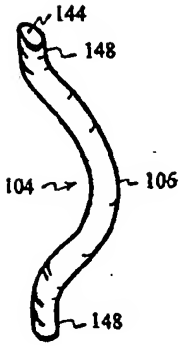


Figure 43

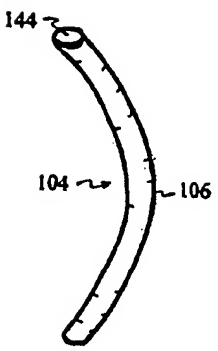


Figure 44

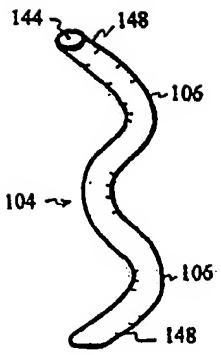


Figure 45

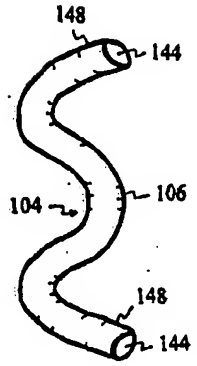


Figure 46

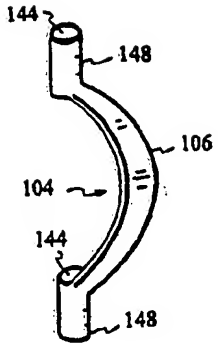


Figure 47

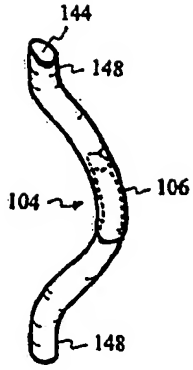


Figure 48

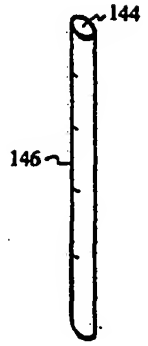


Figure 49

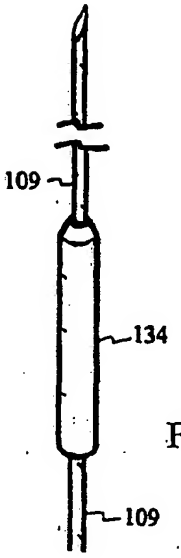


Figure 50

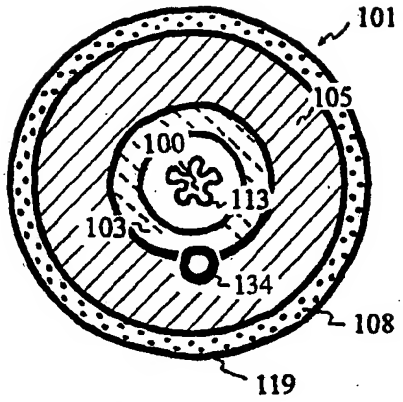


Figure 51

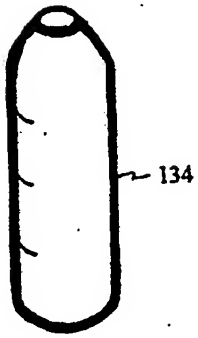


Figure 52

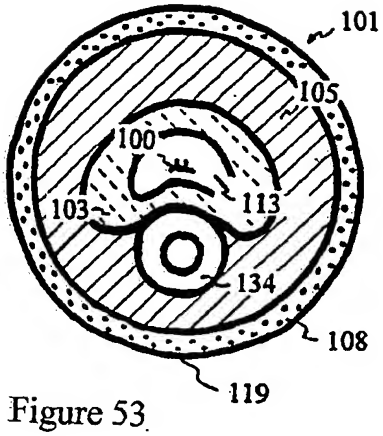


Figure 53

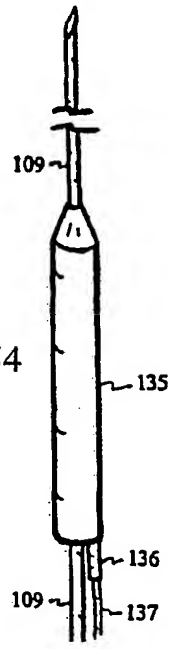


Figure 54

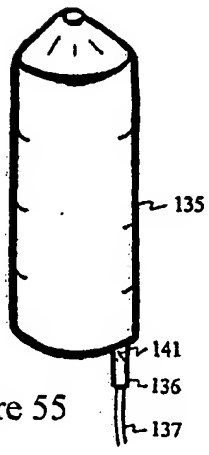


Figure 55

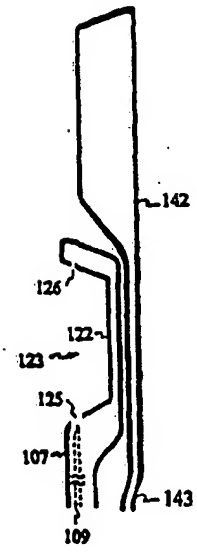


Figure 56

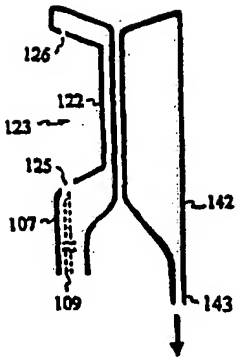


Figure 57

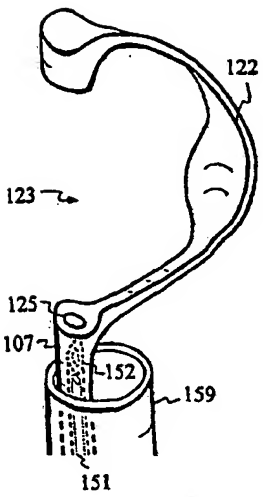


Figure 58

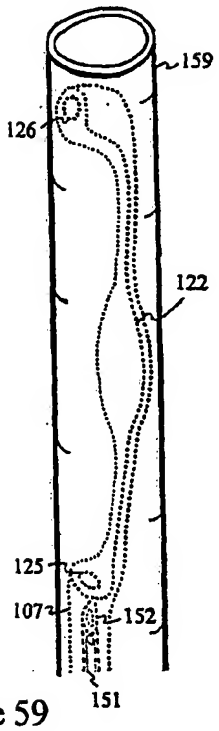


Figure 59

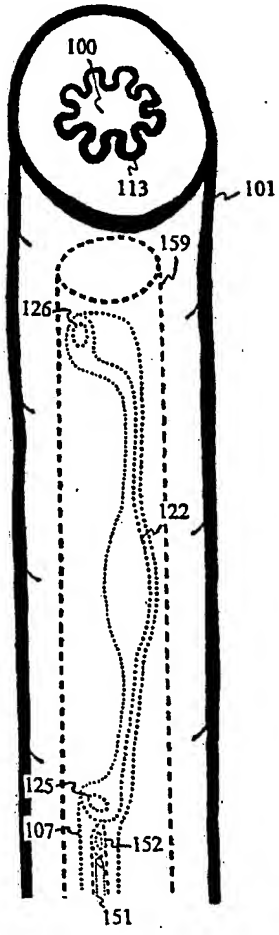


Figure 60

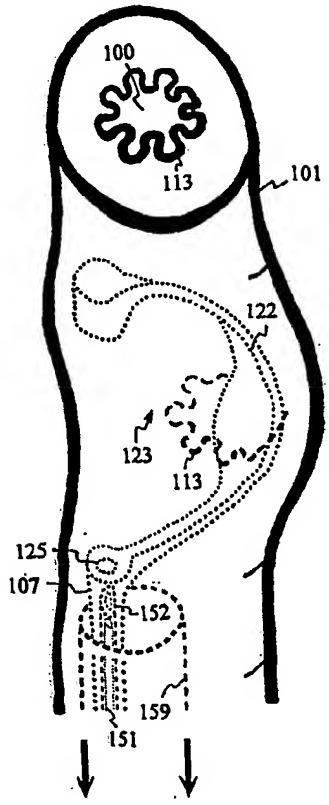


Figure 61

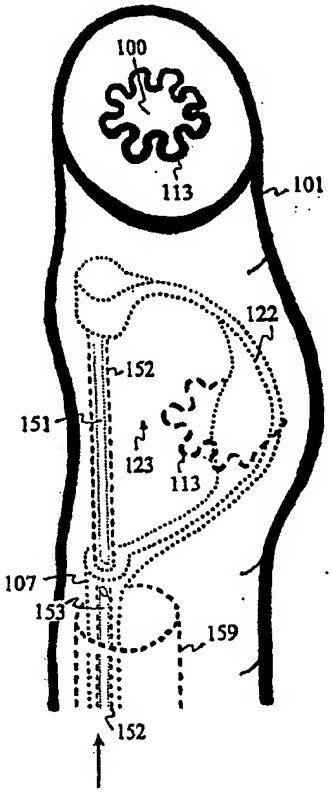


Figure 62

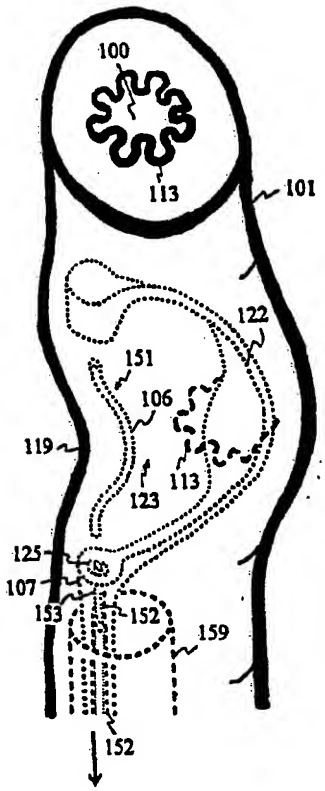


Figure 63

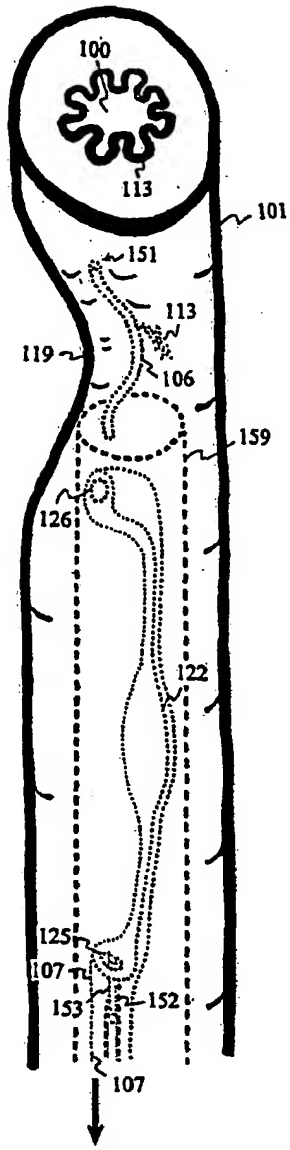


Figure 64

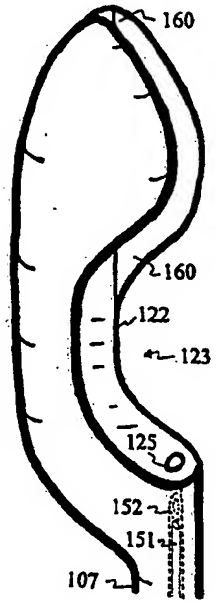
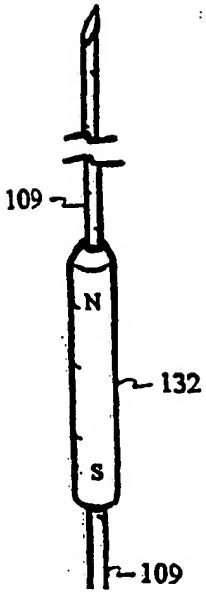


Figure 65



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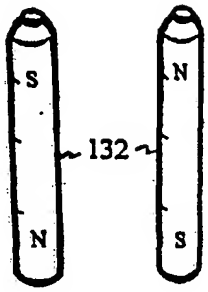


Figure 67

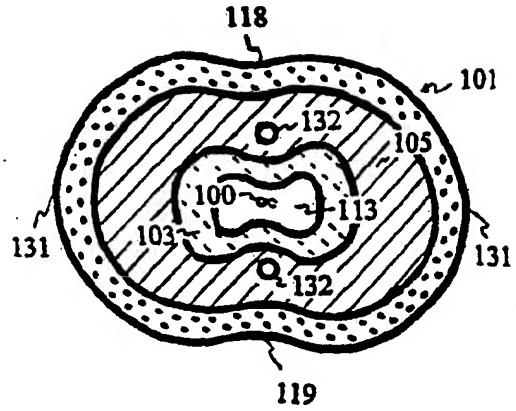


Figure 68

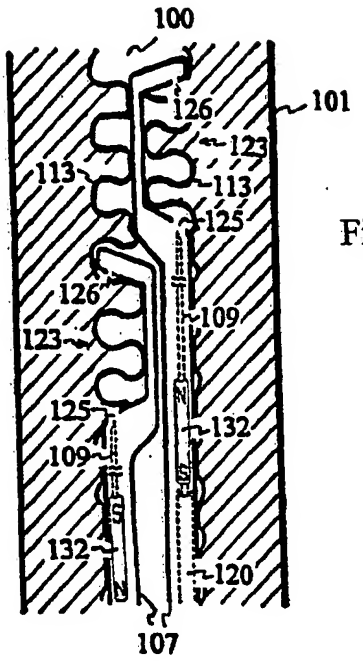


Figure 69

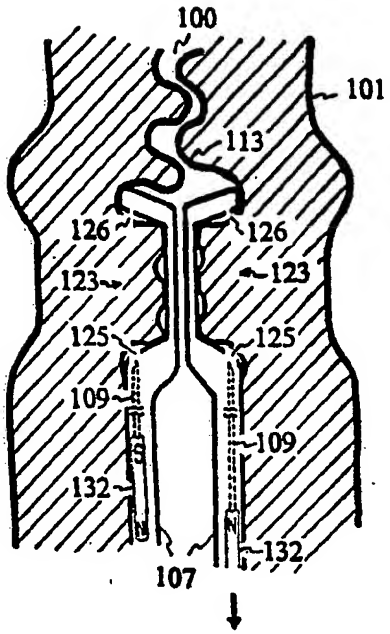


Figure 70

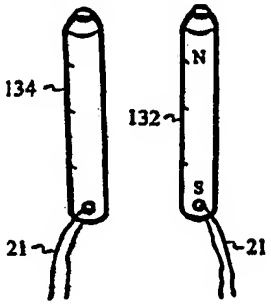


Figure 71

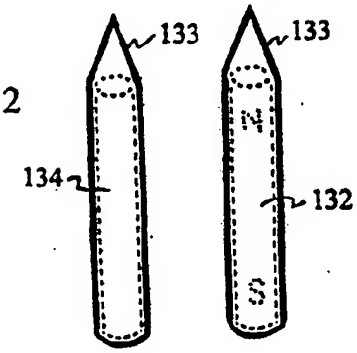
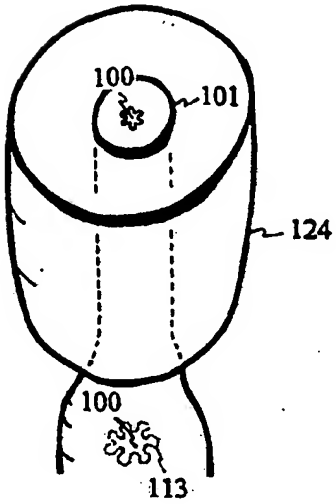


Figure 72



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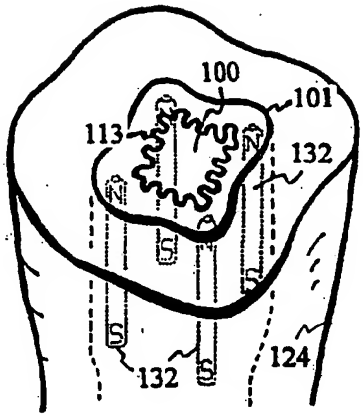

Figure 74

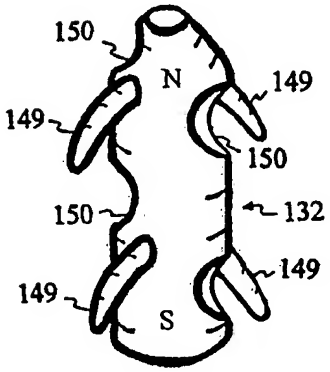

Figure 75

INTERNATIONAL SEARCH REPORT

tional Application No
PCT/US 01/03513

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61B17/128 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 00 40159 A (YEUNG J ET AL) 13 July 2000 (2000-07-13) page 33, line 17 -page 35, line 2 claims; figures 1-6,30,31,50-54,57A-73	1-9, 11-18 19-77
X A	US 5 964 806 A (BURTON JOHN H ET AL) 12 October 1999 (1999-10-12) claims; figures	10 19-77
E	WO 01 26588 A (YEUNG J ET AL) 19 April 2001 (2001-04-19) claims; figures	1
A	WO 98 35606 A (BOSTON SCIENT IRELAND LTD) 20 August 1998 (1998-08-20) claims 1-3,10,14-19,22-24,42-46; figures	1-18

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 February 2002	13.02.02

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kuehne, H-C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

itional Application No
PCT/US 01/03513

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 954 057 A (LI LEHMANN K) 21 September 1999 (1999-09-21) claims; figures	1
A	WO 00 59398 A (ENDONETICS INC) 12 October 2000 (2000-10-12) page 12 -page 15, line 10; claims 5-10; figures 16-18	19,67
A	US 5 562 689 A (SIENKIEWICZ HENRY R ET AL) 8 October 1996 (1996-10-08) claims; figures 14A-B,16A-F	19
A	EP 0 770 365 A (BERBERIAN JEAN PIERRE MARTIAL) 2 May 1997 (1997-05-02) claims; figures	1-77

INTERNATIONAL SEARCH REPORT

ternational application No.
PCT/US 01/03513

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 78-92
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18

A urethral implant comprising:
an elongated body formed of a resilent material, having a first position having a curved configuration and a second position being straighten such that said elongated body is implantable using any implant delivery device,
wherein when the implant is placed within a urethral wall, it is capable of reshaping the urethral wall and thereby faciltating closure of the urethra.

2. Claims: 19-77

A urethral implant delivery system comprising:
an elongated tubular member having a first and second end,
a panel forming a recess connected to elongated tubular member,
a trocar at least partially extendable into said recess,
a handle connected with said second end of said tubular member,
and any urethral implant sized and confirgured to fit within said tubular member.

INTERNATIONAL SEARCH REPORT

tional Application No
PCT/US 01/03513

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0040159 A	13-07-2000	AU 5924099 A	24-07-2000
		EP 1139883 A1	10-10-2001
		WO 0040159 A1	13-07-2000
US 5964806 A	12-10-1999	US 6045498 A	04-04-2000
		AU 8143698 A	30-12-1998
		EP 0996389 A1	03-05-2000
		WO 9856311 A1	17-12-1998
WO 0126588 A	19-04-2001	AU 5598300 A	23-04-2001
		WO 0126588 A2	19-04-2001
WO 9835606 A	20-08-1998	AU 6171798 A	08-09-1998
		EP 1006886 A2	14-06-2000
		JP 2001511686 T	14-08-2001
		US 6099547 A	08-08-2000
		WO 9835606 A2	20-08-1998
		US 6245082 B1	12-06-2001
		US 2001018597 A1	30-08-2001
US 5954057 A	21-09-1999	NONE	
WO 0059398 A	12-10-2000	US 6098629 A	08-08-2000
		US 6338345 B1	15-01-2002
		AU 4205200 A	23-10-2000
		EP 1168976 A1	09-01-2002
		WO 0059398 A1	12-10-2000
US 5562689 A	08-10-1996	US 5507754 A	16-04-1996
		CA 2124651 A1	21-02-1995
		EP 1159920 A2	05-12-2001
		EP 0643945 A2	22-03-1995
		US 5549617 A	27-08-1996
EP 0770365 A	02-05-1997	FR 2740024 A1	25-04-1997
		FR 2740025 A1	25-04-1997
		EP 0770365 A2	02-05-1997